Health Building
Note 29
Pharmaceutical services

MC0131

# Accommodation for pharmaceutical services

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NHS Estates
An Executive Agency of the Department of Health

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## Health Building Note 29

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An Executive Agency of the Department of Health

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# About this series

The Health Building Note (HBN) series is intended to give advice on the briefing and design implications of Departmental policy.

These Notes are prepared in consultation with representatives of the National Health Service and appropriate professional bodies. Health Building Notes are aimed at multidisciplinary teams engaged in:

- designing new buildings;
- adapting or extending existing buildings.

Throughout the series, particular attention is paid to the relationship between the design of a given department and its subsequent management. Since this equation will have important implications for capital and running costs, alternative solutions are sometimes proposed. The intention is to give the reader informed guidance on which to base design decisions.

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# Executive summary

Health Building Note 29 provides briefing and planning advice on accommodation for pharmaceutical services in hospitals.

Since the publication of the first edition of HBN 29 in 1988 the pattern of pharmaceutical services in the NHS has undergone considerable change. Following the loss of Crown immunity in 1991, pharmaceutical manufacturing units have been required to be licensed by the Medicines Control Agency. This has led to a reduction in the number of manufacturing sites, mainly due to the financial costs associated with licensing. At the same time, the use of aseptic dispensing techniques in unlicensed, that is non-manufacturing, sites has grown in line with the increasing range of sterile injections which have to be prepared close to the patient.

Access to pharmacy services has improved in response to the move towards more patient-focused care. It is becoming increasingly common to provide satellite pharmacies in out-patient departments, day surgery units and intensive therapy units. Effective communication with community pharmacists is essential to provide a co-ordinated service for discharged patients receiving follow-up treatment in the primary health care sector.

**This Note describes facilities for:**

**pharmaceutical dispensing services**

- dispensing for in-patients and out-patients
- aseptic preparation and dispensing
- preparation of radiopharmaceuticals
- storing and administering drugs on the ward
- drug information services

**pharmaceutical support services**

- sterile and non-sterile manufacturing
- assembly
- quality control
- purchase and distribution

## Dispensing services

The in-patient and out-patient dispensing service described in this Note is based on two sizes of hospital: medium and large. The dispensary is the hub of the pharmacy department. It should be designed to accommodate new working practices such as the use of automated dispensing systems and the dispensing of items in their original packs rather than from bulk stocks, which may reduce the amount of space required for manipulating prescriptions, but will increase storage areas. In addition, a growing proportion of medicinal products need to be kept in temperature controlled conditions.

The need for security should be borne in mind. All entrances to the pharmacy should be fitted with security locks and an intruder alarm system should be installed. Controlled Drugs should be held in a secure store and the use of computerised prescribing and dispensing systems should be restricted to authorised persons only.

The aseptic facilities described in this Note are suitable for the preparation of a range of products, including intravenous additives, parenteral cytotoxics, and radiopharmaceuticals. Facilities for aseptic dispensing are included in a separate schedule of accommodation, as some dispensaries may already have access to an aseptic suite located in an on-site manufacturing unit. Unlicensed aseptic dispensing should only take place in units whose standards meet 'Aseptic dispensing for NHS patients' and 'The quality assurance of aseptic preparation services'.

All health authorities must provide a drug information service to promote the safe, effective and economic use of medicines and other pharmaceutical products. Each trust will require a technical information room for pharmacy, medical and nursing staff who may wish to consult reference material, but there should also be access, via telephone and computer, to a regional service providing information to community health service staff and the general public.

## Support services

The Department's policy is that the NHS should manufacture pharmaceutical products only if there is no satisfactory commercial source or if it is significantly more economical to do so. The manufacturing unit described in this Note is based on the assumption that it will be producing pharmaceuticals for a number of hospitals in the region. In all areas where pharmaceutical manufacture is undertaken, the premises must comply fully with the guidance contained in Volume 4 of the EEC Guide to Good Manufacturing Practice.

All manufacturing and preparation units must have access to a quality control service to ensure that medicinal products are fit for their intended use. In-process testing facilities will be required for medicines prepared and dispensed in aseptic suites and in units that do not have on-site quality control laboratories.

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# 1.0 Scope of Health Building Note 29

## Introduction

**1.1** This Health Building Note updates and replaces the first edition of Health Building Note 29, published in April 1988.

**1.2** The pattern of pharmaceutical services within the NHS has changed considerably over recent years. As the NHS reforms have resulted in a higher throughput of acute patients, more intensive use of medicines and early discharge of patients into primary health care services, the need for clinical pharmacy services and closer liaison between hospital pharmaceutical services and community pharmacists has increased.

## Hospital pharmacy services

**1.3** The move towards a more patient-focused approach to medical care has had a significant impact on the provision of hospital pharmacy services. Access to the service has been improved by locating satellite dispensaries not only in out-patient departments, but also in day-surgery units, and even on some wards. Access to information is also becoming easier. Patients receive more information about their medicines, both in the form of written instructions contained in original packs, and also from pharmacists who are now spending more time counselling both in-patients and out-patients in the use of their drugs. Another important feature of the pharmacy service is the drug information service which provides information to pharmacy, medical and nursing staff, and the public, at both regional and local levels.

**1.4** The last decade or so has also seen the development of more specialised pharmacists. Clinical pharmacists are spending more time on the wards, assisting clinicians in prescribing decisions, and monitoring drug therapy. The advice of pharmacists is also crucial in the development of the hospital formulary.

**1.5** The economic pressures created by the NHS reforms have touched all aspects of health care, including pharmaceutical services. Pharmacists are under increasing pressure to ensure that the service offers the best possible value for money while not compromising quality. This has resulted in the rise in generic prescribing, which is now widespread in the NHS and which is helping to reduce the total NHS drugs bill. As well as this, cost saving measures are being introduced in the preparation and dispensing of prescriptions: technicians are employed to carry out some of the tasks previously undertaken by pharmacists.

**1.6** Efficiencies are also being achieved through technological developments. The amount of time spent by pharmacists manipulating prescriptions has been reduced by the availability of automated dispensing systems and the introduction of original packs. The tasks of stock control, recording and checking prescriptions have also been simplified through the use of computerised drug prescribing and dispensing systems.

**1.7** Changes in the pattern of pharmaceutical services have not only been restricted to dispensing operations. Following the loss of Crown immunity, manufacturing services in the NHS have undergone considerable change. There has been a general reduction in the number of manufacturing units, consistent with the Department's policy of rationalisation, and, as a consequence, a significant expansion in the aseptic preparation and dispensing of medicines in non-licensed premises.

**1.8** All of these changes (which are described in more detail in Chapter 2) are causing trusts to reconsider the way in which hospital pharmacy services are delivered. Many trusts have contracted out hotel services, and now clinical support services including pathology and pharmacy are under scrutiny. The rationalisation of manufacturing services has already taken place; we may see similar developments in dispensing services in the future. The new structure of the internal market could provide opportunities for one site to supply another, and even for private sector contractors to take on some of the work.

## The interface with community pharmacy services

**1.9** It has been estimated that expenditure on hospital drugs accounts for only 20% of the total NHS drugs budget. The majority of NHS patients get their medicines from pharmacies in the community, and the importance of community-based pharmacies is likely to increase in the future given the policy move towards a primary care-led NHS.

**1.10** Community pharmacists can support the early discharge of patients by providing follow-up care at home. Effective communication between the two sectors about individual patients is crucial. There is often loss of continuity in the medicines prescribed as patients are discharged from hospital. However, the introduction of the new health authorities – which are responsible for hospital, primary and community services –.should result in a more co-ordinated approach to service delivery. The

development of computerised drug prescribing and dispensing systems may also help to overcome these problems by enabling the rapid exchange of up-to-date information on individual patients.

**1.11** The issue of EL(94)72 has led to co-operation between primary and secondary care sectors in the development of formularies. Health authorities are in a position to further encourage consistency in this process so that locally agreed protocols and formularies in general medical practices do not conflict with those in use in hospitals.

**1.12** Many patient groups who were traditionally hospitalised for administration of intravenous medicines or complex therapies may now be cared for at home. Such groups include terminally ill people, patients suffering from cancer, cystic fibrosis or AIDS, and patients requiring parenteral nutrition and peritoneal dialysis. To support such patients at home, specialist pharmaceutical services will need to be developed in the community. The ways in which this may happen are still under discussion but the main options being considered are:

The provision of aseptic preparation and dispensing facilities in community pharmacies (which must meet the same standards as aseptic facilities in hospitals). Aseptic isolators are now small enough to be easily transported and installed in community pharmacies, enabling sterile products, such as intravenous medicines, to be dispensed close to the patient.

The community pharmacist ordering the product from a manufacturer licensed to produce 'specials' and provide the necessary support services.

**1.13** The provision of such specialised services in the community would not only enable all patients to have equitable access to the full range of pharmaceutical services but also encourage greater integration of primary and secondary care services.

## Inclusions

**1.14** This Note provides guidance on the provision of accommodation for pharmaceutical services in hospitals. It describes facilities for:

**Pharmaceutical dispensing services**

dispensing drugs for in-patients and out-patients;

aseptic preparation and dispensing;

the preparation of radiopharmaceuticals;

storing and administering drugs on the ward;

drug information services

**Pharmaceutical support services**

sterile and non-sterile manufacturing;

assembly;

quality control;

purchase and distribution.

**1.15** Although a specific schedule of accommodation for dispensaries in primary healthcare facilities is not provided, the guidance in this Note may be used for planning at a conceptual level. The schedule of accommodation for a remote outpatients dispensing service may be adapted for use in a variety of settings. Project teams should refer to HBN 36 Volume 1 – 'Local healthcare facilities' for guidance on community pharmaceutical services.

**1.16** The guidance in this Note takes into account the advice contained in 'Good manufacturing practice for medicinal products', 'Rules and guidance for pharmaceutical manufacturers 1993', published by the Medicines Control Agency, 'Aseptic dispensing for NHS patients', produced by the Department of Health, and 'The quality assurance of aseptic preparation services' by the NHS Quality Contol Committee.

## Capital Investment Manual

**1.17** The Capital Investment Manual (contains the NHS Executive's procedural framework governing the inception, planning, processing and control of individual health building schemes. There are various mandatory requirements within this overall process but the way these tasks are carried out is mainly for NHS Trusts to determine. Approval from the NHS Executive for business cases will depend on how they intend to carry out the mandatory tasks. The Manual gives guidance on the technical considerations of the full capital appraisal process and also provides a framework for establishing management arrangements to ensure that the benefits of every investment are identified, realised and evaluated. It emphasises three key points:

each individual scheme must be supported by a sound business case. A business case must convincingly demonstrate that the investment is economically sound (through an option appraisal) and financially viable (affordable to the Trust and its purchasers);

an exploration of private finance alternatives should be viewed as a standard option whenever a capital scheme is being considered. Once the Outline Business Case has been approved, the preferred option should be compared to potential private finance alternatives. Approval to the Full Business Case will not be given unless there is a clear demonstration that private finance alternatives have been adequately tested.

the delivery of a major capital project is a difficult and complex task. Nevertheless failure to deliver on time and to cost diverts resources from direct patient care. The establishment of an appropriate project organisation is essential to ensure that projects are delivered within agreed budgets and timescales.

## Cost allowances

**1.18** The Departmental Cost Allowances associated with this Note are promulgated in 'Quarterly Briefing' (issued separately under cover of an Estates Policy Letter) on behalf of the NHS Executive.

## Equipment

**1.19** Equipment is categorised into four groups, as follows:

a. Group 1: items (including engineering terminal outlets) supplied and fixed within the terms of the building contract;

b. Group 2: items which have space and/or building construction and/or engineering service requirements and are fixed within the terms of the building contract but supplied under arrangements separate from the building contract;

c. Group 3: as Group 2, but supplied and fixed (or placed in position) under arrangements separate from the building contract;

d. Group 4: items supplied under arrangements separate from the building contract, possibly with storage implications but otherwise having no effect on space or engineering service requirements.

**1.20** Group 1 items are provided for in the Departmental Cost Allowance associated with this Note. The Department of Health Equipment Cost Allowance Guide (ECAG) specifies a sum of money for the functional unit for Groups 2 and 3; the ECAG does not cover Group 4.

## Works Guidance Index

**1.21** This volume indexes under subject references much of the relevant guidance that is current at the time of publication. Specific issues, such as arrangements for dealing with fire, security, energy conservation, etc., are also covered by other published guidance which must be taken into account. It is recommended that project teams check the current edition of the Works Guidance Index and investigate the possibility of changes occurring since its publication.

## Functional units

**1.22** The functional units in this Note are:

**Pharmaceutical dispensing services**

In-patient dispensing service
- medium-sized hospital
- large-sized hospital

Out-patient service
- attached
- remote

Radiopharmaceuticals

**Pharmaceutical support services**

Sterile and non-sterile manufacturing

Assembly

Quality control

Purchase and distribution

# 2.0 General service considerations

## Purpose of the service

**2.1** The purpose of the hospital pharmaceutical service is to provide the appropriate medication for the patient as authorised by the medical staff. Its activities include:

- dispensing for individual patients, including dispensing certain items aseptically;
- supplying stocks of medicinal products to wards, departments and community health facilities;
- providing advice and information to patients and to medical and nursing staff;
- the manufacture and quality control of medicinal products only where it is economical to do so.

## Licensed and unlicensed sites

**2.2** Since the loss of Crown immunity, hospital manufacturing sites have been required to be licensed by the Medicines Control Agency, under the terms of the Medicines Act 1968. Some medicines, however, may be prepared on an individual patient basis, or for short-term use, under an exemption provided by Section 10 of the Medicines Act. In these unlicensed sites the pharmacist takes full responsibility for the quality of the product.

**2.3** The loss of Crown immunity has resulted in a reduction in the number of manufacturing units and a rapid increase in aseptic dispensing in unlicensed sites. This trend can be explained by the following factors:

- the financial costs associated with licensing manufacturing units;
- the Department's policy to rationalise manufacturing sites, as outlined in HC(84)3;
- the growth in chemotherapy, parenteral nutrition and nuclear medicine has dramatically increased the range of special injections which have to be prepared in aseptic facilities close to the patient.

**2.4** For detailed guidance on licensing, reference should be made to 'Guidance to the NHS on the licensing requirements of the Medicines Act 1968', MCA.

## The pharmacist's role

**2.5** The responsibility of the pharmacist has increased across the spectrum of medicine usage as hospital pharmacy services develop. In addition to their traditional dispensing activities, pharmacists are now developing a clinical advisory role. This may range from assisting clinicians in the treatment of individual patients to contributing at policy level towards the development and maintenance of the hospital formulary. As outlined in HC(88)54, clinical pharmacists may assist medical practitioners in:

- prescribing decisions
- monitoring or modifying drug therapy
- counselling patients on the ward prior to discharge
- clinical trials of medicines

**2.6** Although clinical pharmacists spend much of their day on the wards talking to patients, nursing staff and advising clinicians, they will require a base in the pharmacy department.

## Dispensing

**2.7** Dispensing covers a range of techniques where stocks of drugs or raw materials or both are manipulated to produce a medicine which fulfils the prescribed requirement for an individual patient.

**2.8** Recent developments in dispensing techniques have had a significant impact on working practices in, and consequently the design of, pharmacy dispensaries.

### Original pack dispensing

**2.9** Original pack dispensing means that rather than pharmacists making up each prescription individually from bulk stocks and then labelling it with instructions for use, medicines are bought in from manufacturers in a pre-packed format, with written instructions contained inside the package. The benefits of original packs are that they:

- can be dispensed more quickly and efficiently because they do not require manipulation;
- provide sufficient information to enable patients to be responsible for administering their own drugs;
- can be bar coded, enabling rapid and computerised stock control;
- are generally easy to use in pneumatic tube conveyor systems.

**2.10** The disadvantage is that original packs require significantly more storage space than bulk packs of

medicines. However, since original packs do not require manipulation, this increase in storage space may be partly offset by the reduction in size of dispensary preparation areas.

### Aseptic preparation and dispensing

**2.11** Some dispensed medicines need to be prepared as sterile products. This includes sterile large volume injections which require additional ingredients specific to one patient. Traditionally, these products may have been terminally sterilized, but over the past few years there has been a move towards aseptic preparation and dispensing, as described in paragraph 2.3.

### Automated dispensing systems

**2.12** Automated systems for dispensing drugs can help to increase efficiency in the dispensary by reducing the need for time-consuming manual procedures. Features may include:

- automatic weighing and counting of items such as tablets;
- robotic retrieval systems for ready-to-dispense items;
- bar code scanning;
- computer based operating and monitoring.

**2.13** Dispensary floor areas may need to be increased and strengthened to accommodate the necessary equipment.

## Drug information services

**2.14** A drug information service is required to promote the safe, effective and economic use of medicines and other pharmaceutical products through the provision of accurate, evaluated and unbiased information. Information and advice on medicines, and related issues, should be readily available to community health service staff and the general public. All health authorities should have a designated drug information service to provide local access to evaluated information and impartial advice on all aspects of medicine used within the NHS (refer to paragraph 4.90). In addition to this service, each trust will require a technical information room for the use of pharmacy, medical and nursing staff who may wish to consult reference material (refer to paragraph 4.88).

## Patient counselling

**2.15** Patient-focused care has increased the need to give patients information about their drugs at the time of dispensing. A patient counselling service provides out-patients with the information required for the safe and effective use of their medicines. Counselling must take place in a suitable environment and a dedicated room should therefore be provided for out-patients who request it and for more embarrassing or detailed instructions. Information on drugs for in-patients is contained within the patient information leaflet associated with the product being used. This must be available to the patient on request.

## Manufacturing services

**2.16** The Department's policy on manufacturing is given in HC(84)3 'Manufacture of products in the NHS'. The policy is that the NHS should manufacture pharmaceutical products only if:

- there is no satisfactory commercial source; or
- it is significantly more economical to do so.

**2.17** Detailed information on costing a manufacturing unit is contained in the Appendix to the Circular.

**2.18** The design and planning of manufacturing premises is described in Chapters 3 and 5.

## Quality control

**2.19** A quality assurance and quality control service is essential to ensure that manufactured and prepared medicinal products are fit for their intended use and do not place patients at risk due to inadequate safety, quality or efficacy.

**2.20** All manufacturing and preparation units must have access to a quality control service. Not all units, however, will have their own on-site quality control laboratory, as the cost of equipping such a laboratory can be high. Manufacturing and preparation units that do not have their own quality control laboratory must use outside laboratories. However, a small area will be required on site for carrying out in-process testing (refer to paragraph 4.38). Pharmacy dispensing services will also require in-process testing facilities for medicines prepared and dispensed in aseptic suites.

**2.21** Documentation is an important aspect of quality assurance for products and copies of standard documents are required for each batch. The master document should be stored under the control of the pharmacist in charge of production. The batch records will need to be filled in by staff at many stages in the manufacturing and preparation process, such as weighing, and appropriate facilities should be provided.

**2.22** The facilities required for a quality control service are described in Chapter 5. Project teams should also refer to

'Rules and guidance for pharmaceutical manufacturers', by MCA, and 'Aseptic dispensing for NHS patients', by the Department of Health.

## Purchase and distribution

**2.23** Economies can often be made by centralising in one unit the purchasing and distribution arrangements for a number of hospitals. The unit may also purchase for manufacturing and assembly units, as well as providing a storage service, so an adjacent location would be an advantage. If the unit is to handle materials which are subject to quality control measures it will need facilities for quarantine as well.

## Information technology

**2.24** Information management and technology (IM&T) is fundamental to the successful operation of a pharmacy. A computerised system may be used to control many aspects of a pharmaceutical service, including storage, distribution and quality control.

**2.25** Computerised drug prescribing and dispensing (CDP) is currently being developed to replace hand-written prescription charts in a small number of trusts. With CDP, the act of prescribing a drug sets has three main effects:

- the prescription is stored in patient's computerised record (containing demographic data such as age, weight, diagnosis, allergies, pathology results);
- the prescribed medication is scheduled by the computer to be given at times specified in the prescription;
- if the medication is not stored on the ward, a requisition automatically prints in the pharmacy department;

**2.26** The pharmacist is able to interrogate the patient's computerised record to check the prescription for inaccuracies, drug allergies and interactions before any drugs are dispensed to the ward.

**2.27** The whole pharmacy department should be networked, and the CDP system can be linked to the main hospital computer system to feed information on prescriptions into discharge letters. Links through the wide area network to health authorities, GPs, community pharmacies and the Department of Health will enable the flow of password-controlled information, so that patient medication records and purchases of over-the-counter medicines can be recorded in individual patient records.

**2.28** The main benefits of CDP include:

- fast receipt of prescription;
- more frequent and more complete prescription checks by pharmacists;
- more complete and more legible data on prescriptions;
- more drugs prescribed by their approved name as opposed to their trade name
- formulary management;
- clearer information to nurses when administering drugs
- clearer recording of drug administration.

**2.29** The security of an IM&T system for pharmacy services is a critical issue. Data should only be entered or amended by persons authorised to do so. Suitable methods of deterring unauthorised entry include the use of keys, pass cards, personal codes and restricted access to computer terminals. Personal passwords should be changed frequently.

**2.30** There should be available adequate alternative arrangements for systems which need to be operated in the event of a breakdown.

**2.31** The IM&T system selected should be consistent with local and NHS IM&T strategies which may be obtained from the Publishing Department, DH Distribution Centre, PO Box 410, Wetherby, LS23 7LN (tel: 01937 840250/2). A national overview of the trend towards networking and data communication networking systems is contained in 'A Strategy for NHS-wide networking' which may be obtained from the NHS Executive. More detailed guidance on local area networks (LANs) is contained in the NHS IT Standards Handbook Volume 2 which may also be obtained from the NHS Executive.

**2.32** The choice of systems and matters such as the location of computer terminals, which functions to include on the system, and access levels to information, should be determined locally. Examples of data handling needs which would be met by installation of a comprehensive IM&T network for a pharmacy department include:

- within the department:
  - controlling stock;
  - container labelling and dispensing;
  - providing management information, including clinical audit;
  - managing materials;

  - managing statistical information, including feedback from patients, medical practitioners, nurses, and community pharmacists;
  - storing reference material;
- with other hospital departments:
  - to feed information on patient prescriptions into discharge letters;
- with satellite and community pharmacies:
  - controlling stock
  - managing information;
- with clinicians:
  - receiving prescriptions;
- with GPs:
  - providing information on individual patient care.

**2.33** Project teams should:

- consider the IM&T needs of the department at an early stage;
- review current IM&T developments;
- check that proposals conform with local IM&T policies;
- ensure that sufficient space is provided at the design stage to meet the anticipated need for special power supplies, modems, visual display terminals (VDTs), printers and associated software, stationery, and conduits for cables;
- where necessary and if a suitable space is not available elsewhere, ensure that a room is provided within the department to accommodate the IM&T equipment. The space requirements, temperature limits, etc, should be obtained from the equipment manufacturer;
- ensure that VDT screens are sited so that the displayed text is not visible to members of the public (although it may be considered an advantage to be able to turn the screen to enable the patient to check the accuracy of the information entered);
- ensure that the contents of the VDT screen are legible (see paragraph 8.75);
- ensure that equipment noise is controlled within acceptable limits and, where necessary, fit acoustic hoods or locate the equipment in a separate room;
- ensure that adequate provision is made for the security of data and devices.

## Pharmacy retail outlets

**2.34** With the increasing pressure to generate income, many trusts are developing pharmacy retail outlets for out-patient prescriptions and the sale of non-prescription items. These may be located with other retail outlets in the main hospital concourse, or more conveniently in the out-patients department. Such outlets should comply with Royal Pharmaceutical Society of Great Britain guidelines.

# 3.0 General functional and design requirements

## Location

**3.1** The pharmacy should be located on the ground floor, as many of its functions are dependent on receiving, storing and distributing goods. The pharmacy should be easily accessible to both staff and the public, and should be close to the main hospital routes for easy distribution of pharmaceuticals to wards and departments.

**3.2** The design of the pharmacy department should take into account the supplies distribution system for the whole hospital.

**3.3** The pharmacy stores should be located adjacent to the main goods reception area so that pharmacy staff can take immediate delivery of goods. If stores are sited away from the pharmacy special arrangements would need to be made for a secure transit system of goods.

**3.4** Where pharmacy dispensing services are supported by an on-site manufacturing unit, consideration may be given to sharing an external goods entrance if this can be proven to result in a saving in floor area.

**3.5** The dispensing section of the pharmacy should be located near to the out-patients department. If this is not possible then a satellite dispensary will need to be provided.

**3.6** To avoid cross-contamination the pharmacy should be sited away from departments such as the mortuary and the waste disposal area.

**3.7** The whole pharmacy department should be planned as an integrally secure area with all entrances capable of being controlled. In particular, the total number of entrances from the exterior should be minimised, with attendant supervision to deter unauthorised access. In addition, there should be no corridor traversing the department which is used as a link to other departments.

## Interdepartmental relationships

**3.8** The four main and separated streams of traffic to the pharmacy department are:

- direct receipt of medicines from external sources into the pharmacy stores;
- distribution to in-patients via the ward service area of the dispensing section;
- distribution to satellite dispensaries, peripheral hospitals and clinics;
- prescriptions to out-patients via the out-patient counter.
- Interdepartmental relationships are illustrated in Figure 1.

## Intradepartmental relationships

### Pharmacy dispensing services

**3.9** The dispensary is the hub of the pharmacy department (see Figure 2). Relationships with the out-patients department, stores and drug information service are important and these areas should be planned on the periphery. It is becoming increasingly common to provide satellite pharmacies in, for example, out-patient departments, day surgery units and ITU.

**3.10** Administrative offices should be adjacent to the dispensary for supervisory and communication purposes. Other staff accommodation, however, should not be positioned in the high priority area surrounding the dispensary.

**3.11** The positioning of the aseptic dispensing suite will be influenced by the engineering requirements.

**3.12** In-patient and out-patient dispensing work flows are illustrated in Figure 3.

### Pharmacy support services

**3.13** The industrial nature of a manufacturing service will require it to be located away from the pharmacy, and possibly in a peripheral zone of the hospital site. Manufacturing support services – sterile, non-sterile or assembly – have many common features, such as standard of finishes and engineering requirements, and are thus likely to be located together, which will allow for some sharing of accommodation between the functions.

**3.14** Quality control services are required for both manufacturing and preparation of pharmaceuticals. A separate schedule of accommodation for quality control facilities is provided, as the location of the service will be a matter for local decision.

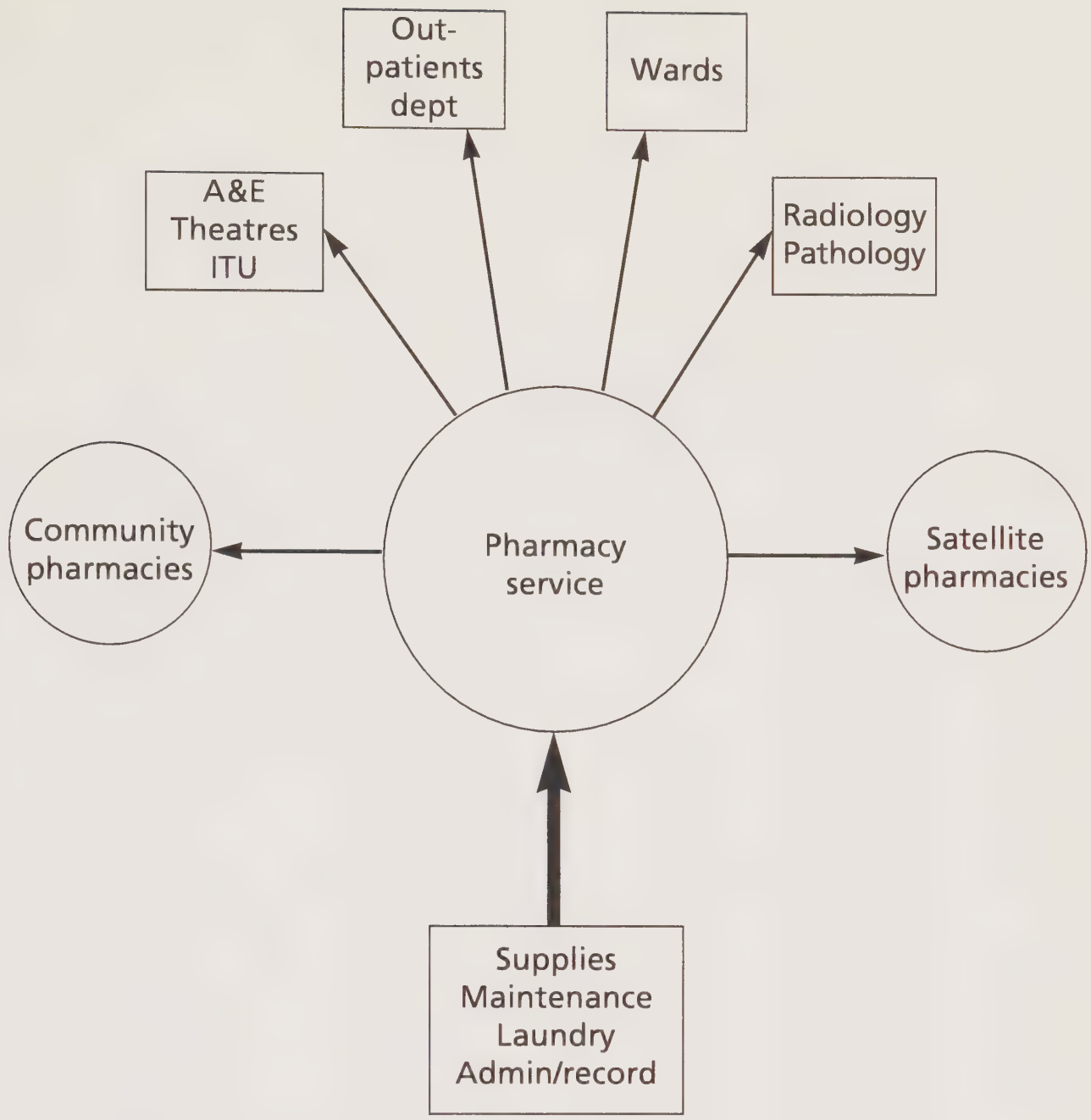


Figure 1: Primary pharmacy service - interdepartmental relationships

**3.15** Although not of a manufacturing nature, a purchase and distribution unit linked to a conjunct manufacturing unit could yield savings in storing and handling the products of the manufacturing unit, particularly bulk fluids.

**3.16** Where facilities are combined to form a conjoint unit the need for good internal communications and flexible provision of accommodation, together with the ability to expand, are of paramount importance. These factors should be borne in mind during the early stages of planning.

## Planning considerations

### Access and security

**3.17** The pharmacy department must be sited so as to be accessible to both staff and the public.

**3.18** The means of access to the pharmacy should be secure. All entrances should have solid doors and be fitted with security locks. Locally agreed arrangements for

**3.18** The means of access to the pharmacy should be secure. All entrances should have solid doors and be fitted with security locks. Locally agreed arrangements for
emergency pharmaceutical cover should be made for occasions when access to the pharmacy is necessary when the department is closed. Hospital emergency cupboards may provide a source of emergency out-of-hours medicines.

**3.19** Security precautions in general should comply with guidance laid down in the NAHAT NHS Security Manual. An intruder alarm system for the department should be installed. It should be linked to the switchboard or direct to the police, and all personnel should be made aware of the locally determined procedure to follow in the event of a breach of security.

### Staff protection

**3.20** Personal alarms or other means to summon help should be provided for all staff, especially those who may be singly manning the department, or working 'on-call'.

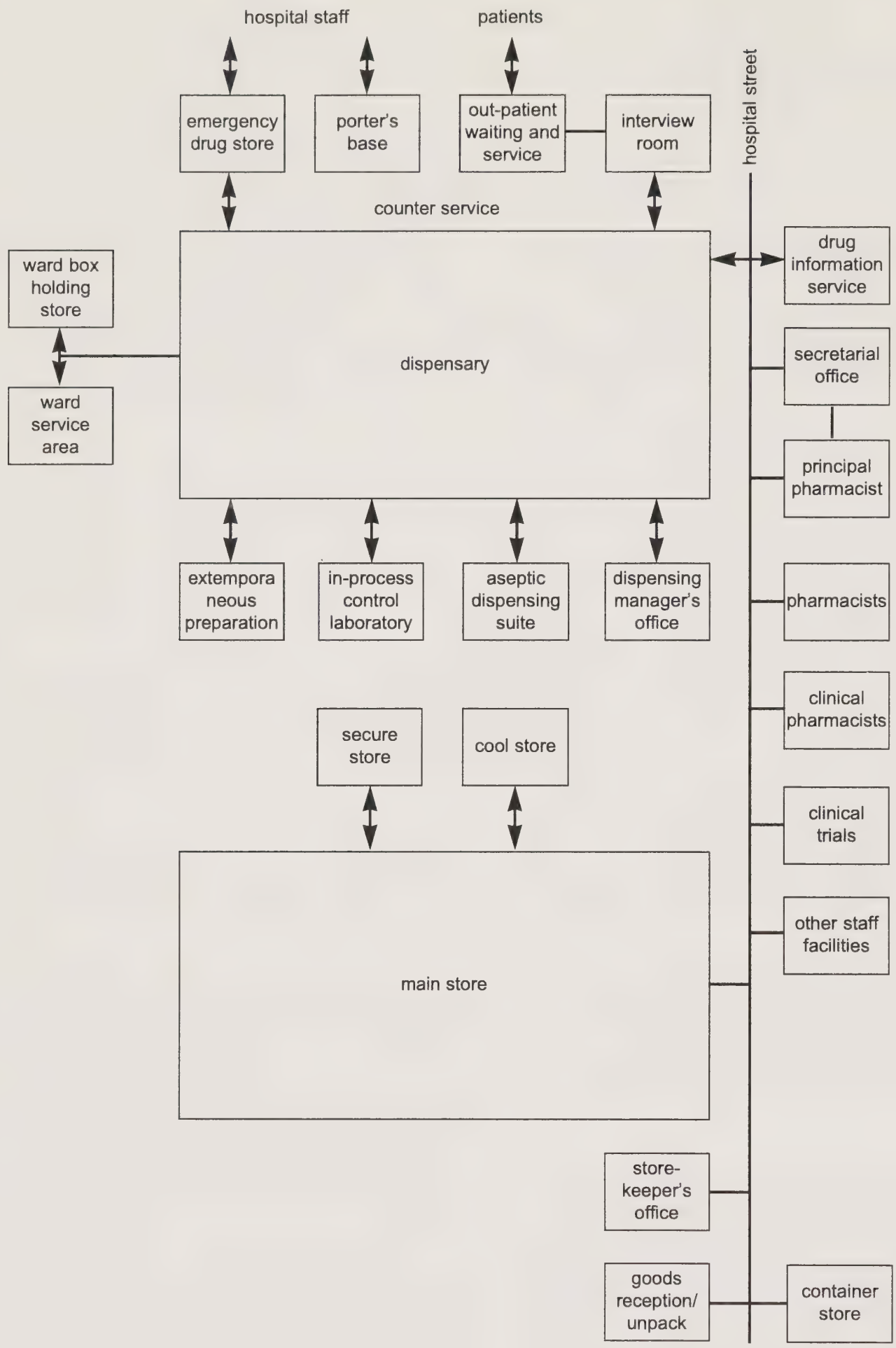


Figure 2: Intradepartmental relationships: flow of staff between main work areas

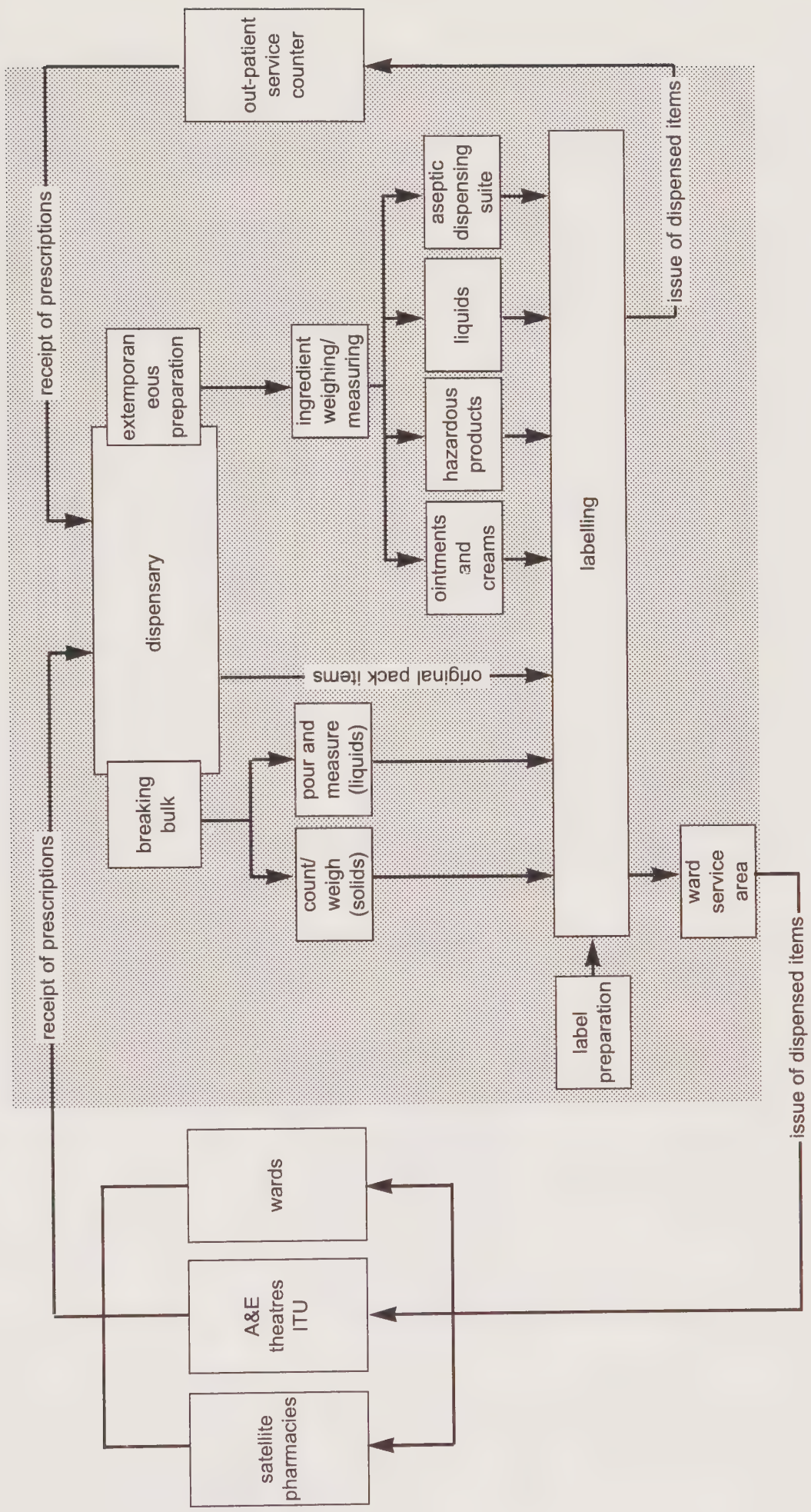


Figure 3: In-patient and out-patient dispensing
*Activities within the pharmacy are indicated by shaded area*

## Aseptic dispensing

**3.21** This Note describes an aseptic dispensing suite which may be used to prepare the following products:

- radiopharmaceuticals;
- parenteral cytotoxics;
- total parenteral nutrition products;
- intravenous additives.

**3.22** An aseptic suite comprises staff changing facilities, an aseptic room and a support room (see Figure 4).

**3.23** Unlicensed aseptic dispensing should only take place in units whose standards meet 'Aseptic dispensing for NHS patients' published by the Department of Health in December 1994. These standards are complemented by 'The quality assurance of aseptic preparation services', published by the NHS Quality Control Committee.

**3.24** Facilities for aseptic dispensing should be designed, constructed and operated in a manner appropriate to the activities undertaken in them and with respect to the equipment installed so that, by segregation and process control, maximum protection can be afforded to the product and, where necessary, to the operator.

**3.25** If common facilities are used for different product types, care must be taken to segregate adequately the activities by time and, where appropriate, specific cleaning arrangements so that cross-contamination is avoided. If alternating product types occurs regularly, consideration should be given to permanently separating the product types by use of a separate clean room or isolator.

## Manufacturing premises

**3.26** In all areas where pharmaceutical manufacture or assembly is undertaken, the premises must comply fully with the guidance set out in Volume 4 of the EEC Guide to Good Manufacturing Practice, and additional requirements of the Medicines Act 1968. For this purpose medicinal products can be divided into sterile and non-sterile, depending upon their intended use.

**3.27** The sterile manufacturing area comprises a clean area with entrances and exits carefully controlled, and ancillary accommodation adjacent. Some ancillary rooms are required for early stages, eg container preparation and ingredient weighing, and others for later stages of production, eg sterilization, inspection and labelling. Verbal communication and visual supervision between the clean area and the ancillary accommodation is essential.

**3.28** The non-sterile manufacturing area prepares solid and liquid medicinal products for oral or external use which are not required to be sterile, such as medicinal mixtures, powders, suppositories, ointments and creams. The bulk of the unit's work takes place in a general purpose preparation area, supported by weighing and container preparation rooms, inspection and labelling area, and quarantine stores.

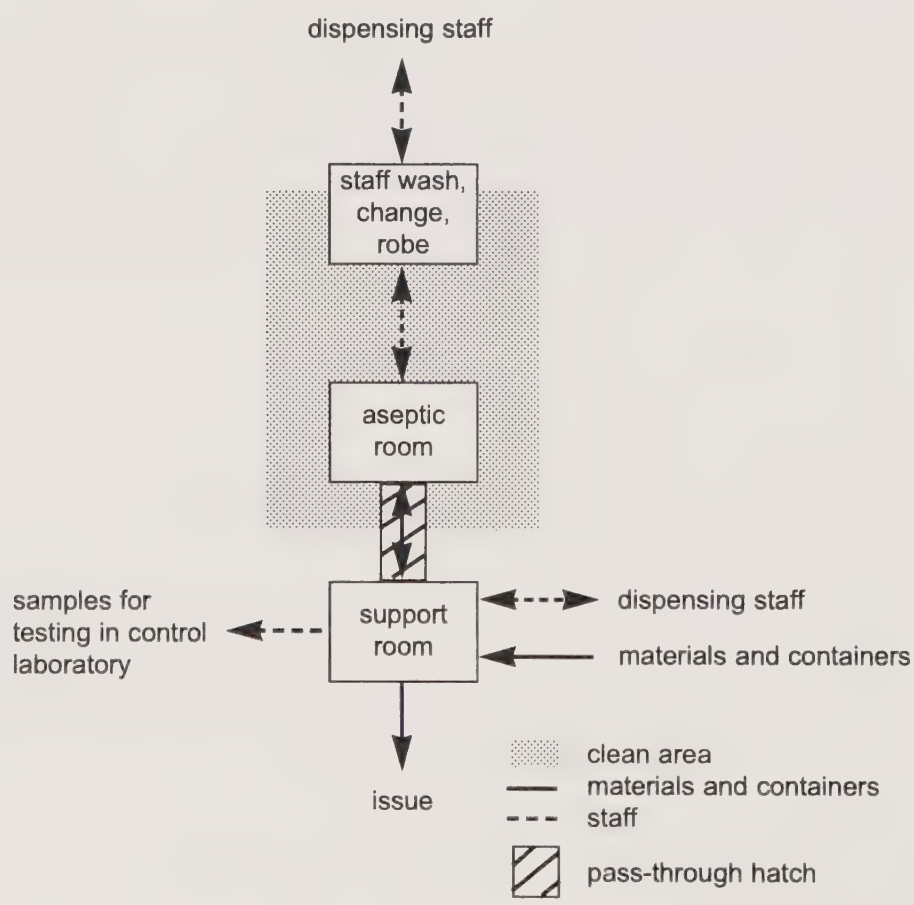


Figure 4: Aseptic dispensing suite

**3.29** For reasons of economy, this Note assumes that sterile and non-sterile areas will be combined in a single manufacturing unit.

**3.30** When designing manufacturing units, project teams should seek the advice of the local medicines inspector.

### Radiopharmaceuticals

**3.31** Radiopharmaceuticals are medicinal products which achieve their diagnostic or therapeutic purpose by virtue of the radioactivity they contain.

**3.32** Many radiopharmaceuticals incorporate radionuclides having short half lives so the preparation, delivery to the clinic and administering to the patient should take place within the working day. This may limit the cost effectiveness of any centralisation within such a service.

**3.33** The radiopharmacy should be located within or close to the nuclear medicine department to reduce problems associated with the movement of radioactive materials around hospitals.

**3.34** The dispensing of radiopharmaceuticals must be under the supervision of a pharmacist. The manufacture of radiopharmaceuticals must be licensed.

**3.35** The design and operation of any radiopharmaceutical preparation facility within a hospital should take into account the particular hazards associated with the radioactive nature of radiopharmaceuticals. The advice of the health authority's radiation protection adviser should be sought. Project teams should comply with:

- The Ionising Radiations Regulations 1985
- The Approved Code of Practice for the Protection of Persons against Ionising Radiation arising from any Work Activity
- Guidance Notes for the Protection of Persons against Ionising Radiations arising from medical and dental use
- The Radioactive Substances Act 1993
- The Radioactive Material (Road Transport) (Great Britain) Regulations 1996
- DHSS Guidance Notes for Hospitals on the Premises and Environment for the Preparation of Radiopharmaceuticals

**3.36** Radioactive products should be stored, processed, packaged and controlled in dedicated and self-contained facilities. The equipment used for manufacturing operations should be reserved exclusively for radiopharmaceuticals.

**3.37** Procedures used in the preparation of radiopharmaceuticals are similar to those used in sterile manufacturing, particularly aseptic dispensing. An extra factor with radiopharmaceuticals however is that there is a range of cold 'kits' available commercially for commonly used preparations. These simplify procedures by making available the required set of sterile reagents or ingredients in rubber-capped multi or single dose vials. A radionuclide generator provides a radioactive solution called the eluate. The simple operation of aseptically transferring an appropriate portion of the eluate from the rubber-capped generator collection vial to a rubber-capped kit vial using a syringe and needle can be regarded as a 'closed' procedure. Some kits may require dilution of the eluate, before addition to the kit vial, with physiological saline supplied in glass or plastic ampoules; this is also considered to be part of a 'closed' system, provided the ampoule is opened only within the required environment, only one withdrawal is made, and the contents are used immediately. Any other procedure, whereby any ingredient of the product is open to the atmosphere before or after sterilisation by not being enclosed in a rubber-capped vial, syringe or other special container, is considered an 'open' procedure and requires more strict preparation conditions. Open procedures with kits are now rare but are still widely used in radiolabelling of blood components, meals for gastric studies and oral preparations for therapy. In the two latter cases sterility is not essential and these preparations do not have to be prepared aseptically. They should be prepared according to the general pharmaceutical standards described in Chapter 5. Materials which are volatile or gaseous should be prepared in a fume cupboard in an unpressurised area.

**3.38** Radiopharmaceuticals given by the parenteral route must be prepared following the standards laid down for aseptic dispensing, as described in Chapter 4.

**3.39** If the radiolabelling of blood products is to be carried out, it must take place in a dedicated facility with an environment complying to EC Grade A, and should be in a room separate to that used for radiopharmaceutical preparation work using kits and generators.

**3.40** In the radiopharmacy working surfaces should be strong enough to bear the weight of lead shielding required.

**3.41** A store cupboard or room suitable for the storage and decay of radioactive waste should be provided away from working areas.

### Storage areas

**3.42** Facilities are required for storing stocks of medicinal products after receipt from suppliers and before being issued for onward distribution to satellite pharmacies, wards, departments, clinics and patients. In manufacturing

units, quarantine storage is required for raw materials, components, finished products and returns. Storage facilities should take into account that:

- a growing proportion of medicinal products need to be kept in temperature controlled conditions;
- items are increasingly being dispensed in their original packs rather than from bulk stock;
- child-resistant and unit-of-use packs require proportionately more space than other packs.

**3.43** Generally, storage conditions should be cool and dry but certain groups of products require more stringent storage conditions in terms of temperature, security or protection from light. The need for stock rotation and regular and thorough cleaning throughout the stores should be kept in mind.

**3.44** Stores must be physically separate from the dispensing area, and receiving and despatch bays.

**3.45** The size of the stores will be determined by local policies on stock ordering and delivery.

**3.46** Controlled Drugs should be stored in cabinets, safes, or rooms which should at least conform to the standards laid down in the Misuse of Drugs (Safe Custody) Regulations.

**3.47** Controlled stationery should be securely kept in the pharmacy under the control of a designated person.

# 4.0 Functional requirements for pharmacy dispensing services and drug information services

## PHARMACY DISPENSING SERVICES

### Dispensary

**4.1** Dispensary staff prepare and compound prescriptions for in-patients and out-patients. Prescriptions may be dispensed:

- as original packs;
- by an automated dispensing unit;
- manually by breaking bulk quantities into small quantities, preparing products from raw materials and then placing into suitable containers and labelling.

**4.2** Most pharmacies use a combination of these three systems to dispense items. Project teams should assess the extent to which each system will be employed, as this will affect the ultimate design of the facility. Advice on the design implications of original pack dispensing and automated dispensing systems is contained in Chapter 2.

**4.3** Plenty of flexible shelving is required for stocks of medicinal products and raw materials. A mechanical system of rotating shelves requires less floor space than fixed shelving. Cupboards and drawers should also be provided, but they should not be located close to heat sources, eg pipes and radiators, which may cause medicines to deteriorate. It is generally preferable to minimise the number of wall mounted or fixed units to allow maximum flexibility for the future.

**4.4** The number of medicinal products requiring cool storage is increasing, and this should be taken into account when determining the number and types of refrigerators to be provided in the dispensary. As refrigerators are constantly being opened and may remain open for some time as staff search for the required product, the temperature rises. The provision of fan-assisted refrigerators with glass doors may help to overcome this problem.

**4.5** Storage will also be required for bottles, lids, cartons and other packaging.

**4.6** Special storage arrangements are needed for Controlled Drugs. If a working stock of Controlled Drugs is required in the dispensary it will require a security cabinet with audio-visual alarms and an alarm connected to a continually manned location. A computer should be provided next to the cabinet for recording the issue of Controlled Drugs (refer also to paragraph 4.57).

**4.7** Electronic counting devices, liquid measures and small balances should be provided, as well as electric socket outlets and washing sinks with hot and cold water. A supply of water will be required for the preparation of some medicines. Clinical hand-wash facilities should be provided.

**4.8** Work surfaces should be level, stable, and affixed to the wall at a suitable height. There should be plenty of room for computer terminals, as the ordering of supplies, stock control, and the recording and labelling of prescriptions will be computerised.

**4.9** An area fitted with stainless steel sinks should be dedicated for the preparation of small quantities of solutions and other 'wet' products. If working stocks of flammable liquids are kept here, a lockable steel cabinet will be required.

**4.10** Special facilities will be required for the production of labels for the dispensed items.

**4.11** If a pneumatic tube conveyor system is installed, a collection point should be provided in the dispensary.

**4.12** A clock with a sweep second hand is required.

**4.13** Fittings and finishes in the dispensary are described in paragraph 7.43.

### Extemporaneous preparation

**4.14** A dedicated space adjacent to the dispensary is required for the compounding of creams and ointments, which may be particularly susceptible to microbial and other contamination during preparation. The room should achieve the air supply criteria of Grade D.

**4.15** Pipework and all items of equipment should be installed so that they may be readily cleaned and if necessary sanitised. The use of glass apparatus should be avoided wherever possible.

### Ward service area

**4.16** A general storage area is required for stocks already issued from the main store. Stocks held here are essential

general items in common use and issued against ward requisition rather than patient prescription.

**4.17** Much of the stock will be held as original packs, so plenty of racking is required. A refrigerator should be provided for those drugs requiring temperature controlled storage.

**4.18** It is usual for staff to print out a computer costed picking ticket and delivery note, which is listed in the order in which items are stored on the shelves. Staff are then able to rapidly select the items and transfer them to the ward boxes. Supermarket type trolleys may be required for staff to use when 'picking' items from the shelves.

**4.19** Direct access to the dispensary and returnable trolley holding store is required. The main pharmacy store should also be easily accessible for bulk stock movements.

**4.20** Controlled Drugs should not be kept in the ward service area, but should be supplied direct from the secure store or dispensary for security reasons.

**4.21** Storage for a working stock of flammables is required. Cabinets with spillage trays should be provided against an external wall.

**4.22** Rather than providing separate accountable stores, project teams may consider designing a single main store for holding general, dispensary and supermarket stocks, which is controlled by computer. This will reduce the amount of time spent physically transferring stock and in effecting the associated computer transactions between stores and distribution sections.

## Ward box/trolley holding store

**4.23** Dispensed items and stocks are sent to the wards, departments and clinics in locked boxes which are later returned empty to the pharmacy. An area is required to hold these boxes, which may include those from wards in other hospitals and from community health clinics. Trolleys will require plenty of space for parking and manoeuvring.

**4.24** Direct access from the dispensary and ward service area is required.

## Aseptic dispensing suite

### Wash/change/robe room

**4.25** Before entering the aseptic room, staff must follow a detailed wash and change routine. They must first remove outer clothing and shoes and store them on the entry side of a step-over bench which marks the boundary between 'dirty' and 'clean' apparel. After stepping over the bench, staff put on special sterilized clothing and footwear already stored in the changing area. Once robed, washed and gloved, staff then enter the aseptic room.

**4.26** A disposal point for used 'clean' clothing, masks and gloves etc should be provided on the 'dirty' side. Protective sterile clothing and gloves, and the suite's own cleaning materials should be stored on the 'clean' side.

**4.27** Changing rooms should be designed as airlocks and used to provide separation of the different stages of changing and so minimise microbial and particulate contamination of protective clothing. They should receive their own supply of filtered air from a ceiling vent. Hand-washing facilities should be provided.

**4.28** Airlock doors should not be opened simultaneously. An interlocking system or a visual and/or audible warning system should be operated to prevent the opening of more than one door.

**4.29** A warning system should be provided to indicate failure in the air supply. Air pressure differences should be recorded regularly.

### Aseptic room

**4.30** To prevent contamination with micro-organisms and particulate matter, aseptic dispensing should be carried out in a laminar flow cabinet equipped with a HEPA filtered air supply complying with Grade A in the EC Guide to Good Manufacturing Practice, situated in a room with a Grade B environment. Alternatively, an isolator providing a similar clean working environment and levels of protection may be used. The background environment in which the isolator is sited should comply with the air quality category defined in 'Isolators for pharmaceutical applications' in accordance with the type of isolator and its transfer system. If an isolator is used, the room in which the isolator is situated should comply with the following requirements:

- it should be an adequate size for the activity;
- no other activity is to take place in the room;
- it should not be a thoroughfare;
- it should be designed for easy cleaning, with a minimum of projecting ledges, shelves, cupboards and equipment;
- it should be suitable for receipt of starting materials and dispatch of finished product;
- it should not have windows that open;
- if it has a false ceiling, this should be sealed to prevent contamination from the space above.

**4.31** Sinks and drains should be excluded from areas where aseptic operations are carried out.

**4.32** The cabinet or isolator must be designed to protect the product, the operator and the environment. Arrangements should be made for the containment of any spillage. Any accidental spillage or contamination of the operator must be dealt with immediately and facilities must be available for the decontamination of the skin, eyes and other surfaces.

**4.33** Laminar flow cabinets and isolators used for products which are hazardous to the operator may operate at negative pressure to the immediate surrounding zone. Validation of such equipment should incorporate checks against extraneous air inflow from the surrounding zone. The equipment should also possess capacity for safe changing of filters.

**4.34** All points of access to and egress from the aseptic room should be fitted with an interlocked or alarmed door system.

**4.35** If radiopharmaceuticals are to be prepared, dedicated and self-contained aseptic dispensing facilities are required. In addition, the premises must meet the requirements for radiation protection (refer to paragraph 3.31). All potentially contaminated waste materials (including syringes, needles and operative's gloves) are collected for separate disposal. The environment must be monitored within the working area for radioactive contamination. Microbiological environmental monitoring must also be performed to ensure continuous assessment of facility performance and operator technique. On completion all preparations must be assayed for content of radioactivity (dose calibration). All preparations which are stable at 2 to 8oCshould be stored in a refrigerator until required.

### Support room

**4.36** Materials and small items of equipment to be used in the aseptic suite will be transferred from the stores to the support room via a pass-through hatch. Solutions to be manipulated in the aseptic room will be prepared in the support room.

**4.37** Materials and equipment will be passed to the aseptic room via an airlock hatch and vice versa. Finished products will be inspected, labelled and held for a short period in this room. Refrigerators will be required for storing the prepared products at 4 to 8oC(except where such conditions would adversely affect the product) to reduce the possibility of contamination.

## In-process control laboratory

**4.38** In the absence of pharmaceutical support quality control facilities, a small laboratory will be required for the in-process testing of some items dispensed in the aseptic suite.

**4.39** Bench space for working and for instruments will be required. A fume cupboard should be provided.

## Out-patient service counter

**4.40** A service counter is required for receiving prescriptions and issuing dispensed items. It should be welcoming with good signage indicating where patients should hand in their prescriptions. If the counter is sectionalised, each function should be clearly signed. At least one section of the counter should be at a height suitable for a person in a wheelchair.

**4.41** Facilities for the collection of prescription charges should be installed. Project teams should consider the provision of a numbered ticket system for patient recall.

**4.42** The need for staff security should be borne in mind. A 'panic button' should be provided.

**4.43** The counter should be immediately adjacent to the waiting area. There should be direct access to the dispensary and the interview room.

## Waiting area

**4.44** A variety of seating is required and should include chairs suitable for older people. There should be spaces for patients in wheelchairs and those using walking aids.

**4.45** Notice boards should be provided for displaying health educational material. Consideration may be given to the provision of television and video facilities for health promotional material and to help alleviate the boredom of waiting. A public telephone should be provided in or near to the waiting area. The provision of vending machines serving hot and cold drinks may be considered.

**4.46** Doors from the waiting area to staff areas should be fitted with keypads for security.

## Interview room

**4.47** A room with natural daylight should be provided for confidential discussions between the pharmacist and patient. It should be furnished comfortably, with a table and easy chairs for up to three people. Entrance from the waiting area should be under staff control.

## External goods entrance

**4.48** A goods reception area with vehicle parking and turning area is required for the delivery of

pharmaceuticals. This area may be grouped with the general external goods entrance for the whole hospital, although there should be direct access to the pharmacy department. A protected loading dock with tailboard access should be provided. Some deliveries may require mechanical handling.

## Goods reception/unpacking area

**4.49** Although the goods reception stores of the hospital may be grouped, a separate area will be required for the reception and unpacking of pharmaceutical supplies.

**4.50** The goods reception store should be adequately ventilated to minimise airborne dust produced when unwrapping parcels. Benches should be fitted at a comfortable working height, and space provided for holding parcels which cannot be unwrapped immediately on delivery. Unwrapping creates an accumulation of used packaging materials which will need regular disposal.

## General store

**4.51** Those products which do not require specialised environmental conditions will be kept in the general store. As pack dimensions vary considerably, adjustable shelving arranged in bays will be required. Adequate floor space should be allowed for the storage of bulky items such as infusion fluids which may be delivered and stored on pallets. Disinfectants and antiseptics should be isolated from other products.

**4.52** The general store should be located adjacent to the goods reception/unpacking area, with easy access to the dispensary and ward service area.

## Temperature controlled storage

**4.53** A walk-in cool store is required for medicinal products which must be stored below ordinary room temperature. A temperature of 6–12°C (summer maximum 15°C) should be maintained by a refrigeration plant which must discharge its waste heat outside the main store.

**4.54** Refrigerators will be needed for storing specific items between 2°C and 8°C.

**4.55** Certain groups of vaccines, sera and other biological products need to be stored in deep freeze conditions (–15°C to 0°C).

**4.56** Temperatures should be continuously monitored with a minimum/maximum thermometer. An alarm system should be installed with visual and audible indicators to the storekeeper's office and dispensary area.

## Secure store

**4.57** Controlled Drugs and medicines which are liable to misuse will need a special security store, accessible to authorised persons only. The store should be a strong-room with space for racks or lockable cupboards. A refrigerator is required. A bench for counting items and recording supplies issues should be provided. An intruder alarm linked directly to a continuously manned location must be fitted, together with a system of external red lights to indicate that staff are working in the store. For further guidance refer to paragraph 8.78.

## Containers store

**4.58** A clean store is required for holding stocks of containers of various types and sizes. Pre-washed plastic bottles and caps will be delivered ready-wrapped.

**4.59** Cleaning arrangements should aim to limit the accumulation of dust.

**4.60** Space for unloading and loading trolleys is required, and there should be easy access from goods reception and unpacking area.

## Dressings store

**4.61** If a dressings store is provided it should meet temperature and humidity requirements. The store should be sited near the goods reception area for distribution direct to wards, departments and clinics.

**4.62** Certain dressings require a product licence under the Medicines Act because they contain medicaments. Since these medicated dressings should be stored and issued only under the control of a pharmacist they are categorised as medicinal products for the purposes of this Note and do not fall under the heading of 'dressings'.

## Flammables store

**4.63** Stocks of flammable materials must be kept away from user areas. The provision of an external isolated store for flammable materials is therefore essential. Local policy may require the pharmacy department to be responsible for holding stocks of flammable materials for other departments as well.

## Medical gas cylinder store

**4.64** An external weatherproof store is required for the range of gases that are supplied in cylinders. If local policy decides that this store should be under the control of the

pharmacy department, access will still be required outside normal pharmacy hours. Advice on the storage of medical gas cylinders is contained in HTM 2022 – 'Medical gas pipeline systems'.

## Emergency drug store

**4.65** The supply of medicines when the pharmacy is closed will be determined by local policy. A store for holding emergency stocks may be required. It should include a refrigerator, an index system and a means of recording which item is taken. A panel for displaying notices should be provided.

**4.66** Ideally the store should be close to the pharmacy (for ease of checking and restocking), but security considerations may make it necessary to site the store near to the main thoroughfare of the hospital or near to an area which is constantly manned.

## Returned medicines store

**4.67** A store is required for holding medicines which have been returned from the wards before they are dispatched for disposal or recycling. A refrigerator will be required. Alternativey, returned medicines may be stored in the general store provided they are segregated from other pharmaceutical products.

## Non-formulary drugs store

**4.68** A store for those medicines not included in the hospital formulary should be provided close to the dispensary. A refrigerator should be provided.

## Unlicensed drugs store

**4.69** A store for holding unlicensed drugs used in clinical trials should be provided. Unlicensed drugs must not be maintained on wards, clinics or in private offices, and must be kept separate from the licensed drugs in the dispensary. Refrigeration facilities and a quarantine area will be required. Alternatively, unlicensed drugs may be stored in the general store provided they are segregated from other pharmaceutical products.

## Principal pharmacist's office

**4.70** The principal pharmacist's office should be sited near the dispensary and be easily accessible for outside visitors. The office should contain a workstation, seating for up to three other people, and shelving and cupboards for storing books and files.

## Pharmacists' office

**4.71** An office capable of accommodating two or more pharmacists will be required. It should be adjacent to the dispensary and be fitted with glazed observation panels. Each pharmacist will require a workstation and storage space for books and files.

## Clinical pharmacists' office

**4.72** Clinical pharmacists working on the wards will require a base in the pharmacy department. Each clinical pharmacist will require a workstation and storage space for books and files.

## Dispensing manager's office

**4.73** The dispensing manager's office should contain one workstation, and seating for two or three other people, as this space may be used for private discussions with patients regarding the use of their drugs.

## Secretarial office

**4.74** An office should be provided for clerical and secretarial staff.

## Clinical trials office

**4.75** An office is required for managing clinical trials on unlicensed drugs. Plenty of space will be required for storing records (of dispensing, issue, administration, and disposal of all medicines), books, files and other documents.

## Storekeeper's office

**4.76** A storekeeper's office is required at the entrance to permit observation of the area. The storekeeper will carry out general clerical duties associated with receiving and storage of supplies. A desk and chair, space for a computer, shelving and storage for files should be provided.

## Porter's base

**4.77** The porter's base should be close to the dispensary and stores. It should be equipped with a table and chair, a telephone, and a locker for storing personal items.

## Cleaner's room

**4.78** Space and facilities must be sufficient for parking and manoeuvring cleaning machines and a cleaner's trolley. A disposal sink, and hand-wash basin, are required. Shelving and vertical storage should be provided.

## Staff change/locker room

**4.79** Personal full length lockers for the secure storage of dry outer and middle garments, footwear and small items of personal belongings are required. Hanging rails, with security, for the storage of wet outer garments and lockers for large items of personal belongings should be provided.

**4.80** A shower should be provided en-suite.

**4.81** The staff change/locker room door should be lockable.

**4.82** The addition of a second staff change/locker room to create separate facilities for male and female staff is a project option.

## Staff sanitary facilities

**4.83** Sanitary facilities, including WCs with hand-wash basins, should be located adjacent to the staff change/locker room.

## Staff room and beverage bay

**4.84** A rest room is required where staff can relax and take beverages and snacks. The rest room should have windows with a pleasant outlook and be comfortably furnished.

**4.85** The rest room should include a beverage bay with facilities for preparing beverages for staff, for washing and storing crockery and cutlery, for storing a limited quantity of dry goods, and for the refrigerated storage of milk, etc.

**4.86** Equipment should include a stainless steel sink and drainer, a refrigerator, an electric water boiler, and a worktop with cupboards.

## Seminar room

**4.87** Recently employed pharmacy graduates, who must complete one year's pre-registration training in practice, will require access to a seminar room for group training and personal study. The seminar room will also be used by student technicians studying for their NVQs. This is essential complementary accommodation (see paragraph 9.10).

# DRUG INFORMATION SERVICES

## Local service

**4.88** A technical information room, sited close to the dispensary, will be required for the ward pharmacy service and also for medical and nursing staff who may wish to consult reference material maintained by the pharmaceutical staff.

**4.89** Telephone or computer links to the regional drug information service should be provided. Workstations are required with space for computerised search facilities, such as CD-ROM. Shelving and storage for books, journals and other reference material should be provided. A direct telephone line must be provided as recommended by the Royal College of GPs.

## Regional service

**4.90** A drug information service is required for answering queries regarding both licensed and unlicensed drugs. The service is primarily for staff in the health authority, but information is freely available to members of the public.

**4.91** Facilities required will include a technical information room (as described in paragraph 4.88), with individual desks for study, some of which may be in cubicles or a separate room for quiet work.

**4.92** Separate office accommodation is required for the pharmacist in charge. There should also be an area for the receipt, cataloguing and preparation of abstracts and periodicals as they arrive.

**4.93** These spaces are listed as essential complementary in the schedules of accommodation.

# 5.0 Functional requirements for support services

## STERILE MANUFACTURING

### Ingredients weighing room

**5.1** Raw materials taken from stores are weighed in the weighing room before being passed directly into the preparation room of the suite via an airlock. The weighing room should be fitted with enclosed balances set up on a level table with a completely firm base. There will also need to be provision for recording the weighings in batch documentation, and for the control of dust.

### Container unpacking and preparation

**5.2** Glass containers from the stores which will need washing should be unpacked before being processed in the container preparation room; the clean containers and closures should be handled only within a Grade C environment. All glass containers are washed in a washing machine, with a final rinse in filtered apyrogenic distilled water, dried and sterilised before passing directly to the filling area; a combined rinse/conveyor system may be used. Belt conveyors should not run between dirty and clean areas; they should stop at the entry to the clean area where bottles then move forward across a static plate. Closures may also be prepared in this room and transferred to the filling area. Pre-washed, ready-wrapped plastic containers do not require washing.

**5.3** The ventilation system should be able to cope with high temperatures and humidity.

### Transfer airlock

**5.4** Consideration may be given to the provision of a larger airlock into the preparation room, capable of taking the movable tanks used inside the suite, with a folding shelf for transferring the smaller items such as pails of closures.

## CLEAN AREA

**5.5** The rooms within the clean area comprise preparation and filling rooms and aseptic rooms together with changing accommodation for staff.

**5.6** Operations in the clean area can be broken down into:

- Preparation
- Filling
- Sterilization
- Inspection and labelling

**5.7** For guidance on construction and finishes in the clean area, refer to paragraphs 7.44 to 7.57.

### Preparation room

**5.8** For terminally sterilized products, solutions are prepared in the preparation room using apyrogenic distilled water and the materials passed in from the weighing room. Solutions may be prepared in mobile tanks with additional mechanical mixing. A sample is taken for a simple in-process test to confirm that it is of the required concentration. The tank is then moved to the filling room, or the solution is pumped there. Cupboards will be required for storage.

### Cleaning bay

**5.9** A cleaning bay should be provided adjacent to the preparation room for washing mobile tanks and other small items of equipment. Containers will be washed with distilled water and then sterilized. The bay also forms the entrance to the aseptic room for materials via an interlocked pass-through cupboard.

**5.10** Facilities for steam cleaning may be considered. A floor drainage channel which discharges to a drain outside the clean area should be provided. A stainless steel sink with elbow-operated taps is required for cleaning other items of equipment. A copper waste pipe is recommended and if possible the trap should be outside the clean area for ease of maintenance.

### Filling room

**5.11** In the filling area for terminally sterilized products, the solution is forced through a clarifying filter and filled into containers which are then capped (bottles) or sealed (bags and ampoules) using heat or radio-frequency welding equipment where appropriate. An alternative method is where a single machine blow moulds plastic containers, fills and seals them. The filled containers are passed to a collection point in the sterilizer loading area either manually via a transfer airlock, or by mechanical conveyor which should not run beyond the boundary of the clean and/or the external area. Drawers should not be fitted in this area.

## Aseptic room

**5.12** Aseptic products are filled in the aseptic room inside a contained workstation. The design of an aseptic room is described in paragraph 4.30.

**5.13** The finished products are passed directly to the inspection and labelling area outside the suite, via an airlock.

## Still room

**5.14** The still room provides a supply of distilled water for the unit's needs, mainly for use in preparation of solutions and in the final rinsing of containers/closures. As the water is susceptible to microbial contamination while stored or in transit, it may be necessary to heat the storage tank(s) to at least 70°C and ensure that piperuns are as direct and internally smooth as possible. Cooling will be required at draw-off points. The following options may be considered:

- stills feeding a single tank located close to the preparation and washing areas, with a short delivery outlet to each;
- twin tanks, each having a single outlet to the area it serves;
- if more than two take-off points are required from a single tank, a recycling ring main is required. It should be fitted with an alarm and have an automatic pump mechanism. Take-off branches should be kept very short.

## Wash/change/robe room

**5.15** Staff enter and leave the clean area via a changing room. Outer garments and footwear are removed on the entry side of a step-over bench. Staff change, wash and put on robes before entering the preparation room and from there the filling room.

## Aseptic wash/robe room

**5.16** The aseptic room must be approached through an additional aseptic changing room, as there is no direct link for personnel between the preparation and aseptic rooms.

## Cleaner's room

**5.17** A cleaner's room is required for servicing the sterile manufacturing unit.

## Laundry room

**5.18** A room for washing or dry cleaning clothing used in the sterile manufacturing unit is listed as optional in the schedules of accommodation, as the need for such a space will be determined by local policy. The laundry service may be provided by an external contractor.

## Sterilization loading/cooling area

**5.19** Products to be terminally sterilized will pass from the filling room of the clean area via a transfer airlock or conveyor. In the former arrangement, the sterilizer trolley is loaded within the filling room and transferred through the airlock via a transfer station located within the airlock itself. In the latter, the trolley is loaded outside the suite. The baskets are loaded into the sterilizer using special sterilizer loading trucks designed to fit the sterilizers used. These trucks can be unwieldy when loaded, so consideration must be given to the space required to manoeuvre them. It is essential that loads before and after sterilization are not mixed; design of this area can assist such separation.

**5.20** Steam and hot air sterilizers should comply with HTM 2010 – 'Sterilization' and be sealed into the wall to present a flat, easy-to-clean surface incorporating gauges, controls and thermocouple ports.

**5.21** After sterilization, a period of cooling may be required before the batch can be passed on for inspection; a separate area should therefore be set aside for parking the trolleys with their trucks.

## Inspection and labelling area

**5.22** This area should include facilities for inspecting under polarised light and for batch-numbering the labels. When the labels have been prepared and fixed, the items are loaded into crates or boxes; they may additionally be loaded onto pallets and shrink wrapped. Each batch must then wait in the quarantine store for quality control clearance before being passed to the finished products store.

# NON-STERILE MANUFACTURING

## Ingredients weighing room

**5.23** Raw materials taken from stores are weighed in the weighing room before being passed directly into the preparation areas. The weighing room should be fitted with enclosed balances (generally larger than those required for sterile manufacture) set up on a level (slate) table with a completely firm base. There will also need to be provision for recording the weighings in batch documentation.

## Container unpacking and preparation area

**5.24** Containers from the stores which need washing should be unpacked before being processed in the container preparation room; the clean containers and closures should be handled only within a Grade C environment. All glass containers are washed in a washing machine, with a final rinse in filtered apyrogenic distilled water, before passing to the filling areas. Pre-washed, ready-wrapped plastic containers do not require washing.

**5.25** The ventilation system should be able to cope with high temperatures and humidity.

## Changing room

**5.26** A small room is required where staff may wash their hands and put on clean coats before entering the preparation areas.

## Dry and liquid products area

**5.27** Since both solid and liquid products will be prepared in this area it must allow for sufficient flexibility of use in response to demand. The bulk manufacture of liquid products requires large mobile tanks, with mixing equipment which could be free standing or clamp held. Workbenches will be required for preparing smaller batches of liquids.

**5.28** Depending on the nature and quantity of materials to be produced, project teams may consider partitioning the area into cubicles and installing local dust extraction to prevent cross-contamination.

**5.29** Dry products or small quantities of liquids can be placed in containers in this area. Large tanks of liquids, however, should be handled in a separate area (refer to paragraph 5.35).

## Creams and ointments room

**5.30** The preparation of creams and ointments – which may be particularly susceptible to microbial and other contamination during manufacture – should be carried out in a dedicated space which satisfies the air supply criteria of Grade D. Small batches can be prepared on an electrically heated slab mounted on or inset into a worktop. Larger quantities may require the use of steam heated pans, industrial mixers and special filling machinery.

**5.31** Pipework and all items of equipment should be installed so that they may be readily cleaned and if necessary sanitised. All pipework should be clearly identified. The use of glass apparatus should be avoided wherever possible.

## Hazardous dry products room

**5.32** The large scale mixing of dry powders, or processing of other materials harmful to the operator, may require a separate room operating under negative air pressure.

## Flammable materials room

**5.33** A separate manufacturing area will be necessary for mixing and filling flammable materials. It should be equipped with suitable fume extraction and comply with all relevant safety requirements.

## Cleaning bay

**5.34** A bay is required adjacent to the preparation area for cleaning equipment and scouring out the large tanks.

## Bulk liquid filling area

**5.35** A separate area is required for filling containers from large tanks of liquids. An industrial filling machine may be installed here. The environment should be controlled by providing mechanical ventilation through coarse filters (the recommended level of filtration is EU7 with 8-12 air changes per hour).

## Inspection and labelling area

**5.36** Finished products are moved into a separate area for visual inspection and labelling. A bench may provide a convenient boundary and assists hand labelling, although a free-standing labelling machine may be used. For large batches, shrink-wrapping and pallet equipment may be required. Products will then be transferred to the quarantine store to await quality control clearance (refer to paragraph 5.37).

## MANUFACTURING STORES

### Quarantine store

**5.37** Quarantine is a method of holding a batch of materials in store whilst awaiting the results of quality control testing; the materials being issued for use if acceptable or destroyed or reprocessed if unacceptable. The quarantine store should be large enough to accommodate raw materials, components, finished products and returned materials, each of which should be held in a separate area of the store. Refrigerators will be required for some products.

**5.38** Finished sterile products may be held in quarantine for up to four weeks. The space needed for holding products will therefore vary according to the unit's capacity and product mix.

### Materials store

**5.39** Once passed for use in production, raw materials are transferred from the quarantine store into a materials store until required. A refrigerator should be provided.

### Consumables/equipment store

**5.40** Storage will also be needed for other materials involved in manufacturing, eg small quantities of production consumables like filters and cleaning materials.

### Containers store

**5.41** Empty containers need a great deal of space. Clean containers should be held separately from those awaiting cleaning, and the sorting and disposal of rejected returned containers should be performed away from other activities. Consideration should be given to the separate quarantining of containers.

### Finished products store

**5.42** On release from quarantine, the finished items are passed to the finished products store. A refrigerator should be provided.

**5.43** Secure label storage, such as lockable cupboards, will be required, with restricted access. Storage arrangements should ensure that the risk of label mix-up is minimised.

### Flammables store

**5.44** Bulk flammable materials must be kept in a flammable store away from the main building. This store is essential complementary accommodation.

## MANUFACTURING SUPPORT SPACES

**5.45** The following support spaces will be required in the manufacturing unit:

- Pharmacist's office (see paragraph 4.71)
- Staff room and beverage bay (see paragraph 4.84)
- Cleaner's room (see paragraph 4.78)
- Staff change/locker room and sanitary facilities (see paragraph 4.79 to 4.83)
- Switchroom

## ASSEMBLY

**5.46** The function of this support unit is to repackage items in a form suitable for patient use. It is assumed that only bought-in products will be repackaged in this unit.

### Container preparation area

**5.47** An area is required for collecting, sorting, washing and preparing containers. Refer also to paragraph 5.2.

### Unpacking area

**5.48** Products should be unpacked in a separate area, as exposed products will need protecting from debris derived from the outer packaging of empty containers. Facilities will be required for the disposal of waste packaging material.

### Tablet packing area

**5.49** A multi-purpose work area is needed, with a range of equipment such as counting aids for tablets and capsules or strip packing machinery. Potent or sensitising products such as uncoated penicillin tablets or steroid products will require special safeguards, such as local dust extraction. Where the throughput of such products is large, dedicated equipment may be needed to avoid contamination of other products. Simple movable partitions between individual workstations can reduce the risk of a product mix-up in a busy unit. If a large scale packing line is to be used it should be installed in a separate room with appropriate dust extraction.

## Liquid filling area

**5.50** Facilities for filling liquids should be kept separate from other functions. The environment should be controlled by mechanical ventilation.

## Creams and ointments area

**5.51** Creams and ointments should be handled in a dedicated area supplied with Grade D filtered air.

## Flammable materials area

**5.52** Flammable materials should be repackaged in a separate area.

## Visual inspection and labelling area

**5.53** Labelling procedures similar to those for manufacturing will apply. Simple visual inspection on completion should suffice so a quarantine store would not normally be required.

## Equipment cleaning room

**5.54** Although much of the equipment would be cleaned in situ, an area with a stainless steel sink having hot and cold water services should be set aside for washing smaller items and parts of large equipment.

## Stores

**5.55** The following stores will be required in the assembly unit:

- Materials store (paragraph 5.39)
- Clean equipment store (paragraph 5.40)
- Containers store (paragraph 5.41)
- Packed products store (paragraph 5.42)

## Pharmacist's office

**5.56** The pharmacist in charge will require an office with a workstation and storage for books and files (refer also to paragraph 4.71).

## Cleaner's room

**5.57** Space and facilities must be sufficient for parking and manoeuvring cleaning machines and a cleaner's trolley. A disposal sink, and hand-wash basin, are required. Shelving and vertical storage should be provided.

## Staff change/locker room

**5.58** Personal full length lockers for the secure storage of dry outer and middle garments, footwear and small items of personal belongings are required. Hanging rails, with security, for the storage of wet outer garments and lockers for large items of personal belongings should be provided.

**5.59** A shower should be provided en-suite.

**5.60** The staff change/locker room door should be lockable.

**5.61** The addition of a second staff change/locker room to create separate facilities for male and female staff is a project option.

## Staff sanitary facilities

**5.62** Sanitary facilities, including WCs with hand-wash basins, should be located adjacent to the staff change/locker room.

# QUALITY CONTROL

## Chemical testing laboratory

**5.63** The laboratory should be fitted with continuous, heat and chemical resistant work surfaces. Under-bench units are required for storing small items of equipment and glassware. The worktops should provide for several workstations, each within easy reach of services outlets and a small sink. Glassware washing facilities are required.

**5.64** Although bulk quantities of flammable and volatile solvents should be stored separately in an external isolated store, daily working stocks should be stored in a special fire-resistant cupboard with tray shelves to contain spillage. A second fire-resistant cupboard, fitted with welded epoxy resin liner and also dished to contain spillage, should be provided for storing acids. Other reagents will be stored on adjustable wall shelving or in refrigerators as necessary.

**5.65** An emergency shower for accidental spillages should be provided.

**5.66** The chemical testing laboratory may be combined with the instrument laboratory described in paragraph 5.68.

**5.67** For guidance on fume cupboards, refer to paragraph 8.35. For further guidance on the design of laboratories, reference should be made to HTM 67 – 'Laboratory fitting out systems', and Fire Practice Note 10 – 'Laboratories'.

## Instrument laboratory

**5.68** Adequate worktop space is required on which to stand the instruments. As some of them may be very heavy, the worktop must be properly supported throughout its length. Under-bench storage should be provided.

**5.69** Each instrument has varied service requirements which should be borne in mind when planning.

**5.70** The instrument laboratory may be combined with the chemical testing laboratory described in paragraph 5.64.

**5.71** For further guidance on the design of laboratories, reference should be made to HTM 67 – 'Laboratory fitting out systems'.

## Weighing area

**5.72** Weighing facilities should be shared by the chemical and instrument laboratories and should be sited away from draughts, preferably in a separate room convenient to both. Several balances of varying capacities will be required, all firmly installed on a flat table to minimise vibration.

## Laboratory workshop

**5.73** A small workshop may be required for assembling new items of equipment, or for repairing apparatus. This is optional accommodation (see paragraph 9.12).

## Microbiological testing suite

**5.74** If microbiological testing is to be undertaken, a separate suite designated for this purpose will be required, comprising a test room and ante room. The construction and finish of such a suite should be broadly comparable to that of a clean area although with a less stringent requirement for air supply. This suite is essential complementary accommodation (see paragraph 9.10).

### Test room

**5.75** The test room is primarily for sample and inoculation manipulations but a pouring bench could be incorporated if media plates are to be prepared locally. The test room will need an air supply to Grade C.

### Ante room

**5.76** The ante room contains incubators and equipment for colony counting as well as sterilizing equipment for media and for disposal purposes. Handwashing facilities and storage for clean garments, gloves etc should also be provided, but not to the standard necessary for sterile manufacturing or dispensing purposes. The air supply should be Grade D.

## Reference sample store

**5.77** Reference samples of raw materials and of items manufactured by the pharmaceutical support services should be kept for an appropriate period. A separate locked store should be reserved for this purpose as part of quality control; its environment and fittings are similar to those of a general pharmacy store and a refrigerator will be required for certain small items. Special arrangements must be made if samples of Controlled Drugs are being kept for reference purposes.

## Pharmacist's office/sample reception

**5.78** The pharmacist's office should be sited to allow oversight of the work of the laboratory staff. This may require the provision of internal windows. The office may also be used for sample reception and associated paperwork.

**5.79** Records and other documents have to be retained for at least two years, and adequate storage space should be provided in lockable cabinets.

## Support spaces

**5.80** The following support spaces will be required in the quality control unit:

- Cleaner's room (see paragraph 4.78)
- Staff room and beverage bay (see paragraph 4.84)
- Staff change and WC (see paragraphs 4.79 to 4.83)
- Switchroom

# PURCHASE AND DISTRIBUTION SERVICE

## External goods entrance

**5.81** The bulk of materials likely to be handled makes it desirable to provide an exclusive unloading bay, off a suitable access road. The bay should have direct access to the unit's goods reception and unpacking area and be

approachable directly from the despatch assembly area. It should be protected against the risk of contamination from outside sources.

## Goods reception and unpacking area

**5.82** The reception and unpacking of supplies will play a more important part in the unit's workflow than in a pharmacy department providing solely for patient services.

**5.83** The goods reception area should be adequately ventilated to minimise airborne dust produced when unwrapping parcels. Benches should be fitted at a comfortable working height, and space provided for holding parcels which cannot be unwrapped immediately on delivery. There should be easy access to despatch assembly and the refuse collection area.

## Despatch assembly area

**5.84** An area is required for collecting together goods for delivery. It should be under direct supervision from the pharmacist's office.

**5.85** Worktops are required for wrapping and packing goods. Racks should be provided for holding goods for distribution.

**5.86** The assembly area should be sufficiently large for pallet trucks to manoeuvre safely. Space may be required for wrapping machines.

## Refuse collection area

**5.87** The disposal of considerable quantities of waste packaging materials needs to be considered at an early stage and an external collection point is recommended.

## Stores

**5.88** The unit would not be expected to stock flammable materials or medical gas cylinders unless it is directly associated with the hospital pharmacy service. A centralised service needs to handle a larger quantity of each type of goods, perhaps several times more than that held at hospital level; transfusion fluids in particular would require a large amount of space. It may be decided that the unit should not stock particular items, eg Controlled Drugs (for security reasons) and such considerations would modify the facilities required.

**5.89** A further function the unit could perform would be to collect from dependent pharmacies any items due for return to manufacturers, such as products subject to a recall. It might be necessary to set aside a separate, secure area for this task.

## Staff accommodation and support spaces

**5.90** Staff accommodation should include a portering base and office accommodation for the pharmacist in charge and clerical staff (with facilities for storing the purchase records etc). Facilities for computer equipment will be required, also parking/recharging space for the trolleys and mechanical handling equipment.

# 6.0 Functional requirements for the storage of drugs on the ward

## Ordering and distribution of stock

**6.1** Most hospital pharmacies use the technician top-up system for distribution of drug stocks to wards. Typically this accounts for about 80% of drug usage, and involves ward boxes being delivered to the pharmacy and then to the wards. The other 20% of deliveries generally take place through individual patient supply from the dispensary area and typically return to the wards via a portering system. There is usually a storage area in the dispensary for the dispensed drugs awaiting collection by the porter or a member of the ward staff. If pneumatic tube systems are widely introduced then the whole ward delivery system would be dramatically affected (apart from large volume fluids, sensitive materials etc, which are not suitable for use in pneumatic tubes).

**6.2** The appointed nurse in charge or a member of the pharmacy staff will be responsible for ordering medicines from the pharmacy for maintaining ward stocks and for individual patients. Orders should be made electronically, and computer systems should be password protected to ensure security.

## Storage

**6.3** Separate lockable ward cupboards are required as follows:

- Controlled Drugs cabinet
- internal medicines cupboard
- external medicines cupboard
- refrigerator/freezer for medicines

**6.4** Separate storage should also be provided as follows:

- cupboard for diagnostic reagents, including urine testing;
- area for intravenous fluids and sterile topical fluids;
- area for flammable fluids and gases.

**6.5** In intensive therapy units, drugs should be kept in a designated cool area, as the ambient temperature on the ward is higher than desirable for the storage of a large range of drugs.

**6.6** In accident and emergency departments, drugs should be located in areas where there is constant vigilance. The use of CCTV should be considered.

**6.7** Drug cupboards to be used for internal and external medicines should comply with BS2881.

**6.8** The use of ward drug cupboards that make an automatic record of any withdrawal and send a corresponding replenishment order to the pharmacy is likely to increase in the future. Such technology offers a secure and efficient topping-up system.

**6.9** Further guidance on storage in clean utility rooms is contained in HBN 40, Volume 3 – 'Staff areas'.

**6.10** New practices for self-administration of medicines have developed as patients have been actively encouraged to participate more in their own treatment. When there is self-administration of medicines on the ward, each patient should have a lockable receptacle (eg, drawers) which is not readily portable.

**6.11** For clinical emergencies, eg cardiac arrest, all wards should have a source of urgent supplementary medicinal products. These should be held in boxes clearly marked 'for emergency use'. These boxes should be tamper-evident and should not be held in a locked cupboard, but at strategic and accessible sites.

# 7.0 Other general functional and design requirements

## Introduction

**7.1** This chapter contains additional guidance on aspects of function and design which are common to all health buildings.

## Statutory and other requirements, including Crown immunities

**7.2** The guidance takes account, as far as possible, of all statutory and other requirements in force at the time of publication. However, health authorities and trusts are reminded of their responsibility for ensuring compliance with all relevant statutes, regulations, codes and standards.

**7.3** Building and planning law are legally enforceable on the NHS. Guidance on the removal of Crown immunity is given in Circular HN(90)27/LASSL (90)15 (in Wales, WHC(91)4, and in Scotland NHS Circular 1991(GEN)1), in respect of a wide range of legislation.

## Building components

**7.4** The Building Components Database consists of a series of Health Technical Memoranda (HTMs) 54-70 which provide specification and design guidance on building components for health buildings which are not adequately covered by current British Standards. No firms or products are listed. The numbers and titles of the various HTMs in the series are listed in the 'References' section at the end of this Note.

## Upgrading or adaptations of existing buildings

**7.5** The standards set out in this guidance apply to the provision of accommodation by new building. However, the principles are equally valid and should be applied, so far as is reasonably practicable, when existing accommodation is being upgraded or new accommodation is being constructed within an existing building which may previously have been used for other purposes. Compromises may have to be made between Health Building Note (HBN) standards and practicability.

**7.6** Before a decision is made to carry out an upgrading project, consideration must be given to the long-term strategy for the service, the space required for the new service, and the size of the existing building. Regard must also be paid to the orientation and aspect of the building, and the extent to which key HBN requirements can be met: for example, the need for accommodation with ground level access, and the adequacy and location of all necessary support services.

**7.7** If a prima facie case for upgrading emerges, the functional and physical condition of the existing building should be thoroughly examined. The check of physical and other aspects of existing buildings should include consideration of:

- overall availability of space for alterations and additions;
- type of construction; including constraints to adaption, for example, load bearing/non load bearing structures;
- insulation;
- age of the buildings and condition of building fabric – for example, external and internal walls, floors, roofs, doors and windows – which may be determined by a condition survey;
- life expectancy and adequacy of engineering services, ease of access and facility for installation of new wiring, pipework and ducts, if required;
- the height of ceilings;
- changes of floor levels;
- fire precautions;

**7.8** When comparing the cost of upgrading or adapting an existing building to that of constructing a new building, due allowance – in addition to the building cost – must be made for the costs of relocating people, demolition, salvage, disruption of services in a phased project, and the temporary effects on running costs of any impaired functioning of areas of the building affected by the upgrading works.

**7.9** The cost of upgrading work should conform to the guidelines which were originally promulgated in the Department's WKO letter (81) 4, and more recently referred to in Volume 4 of the NHS Estates Quarterly Briefing. Those guidelines take into consideration the estimated life of the existing building and the difference in cost between upgrading a building and constructing a new building.

## Smoking

**7.10** NHSME circular HSG(92)41, entitled 'Towards smoke-free NHS premises', promulgates Government policy set out in the 'Health of the Nation' White Paper, and required NHS authorities and provider units to implement policies so that the NHS became virtually smoke-free by 31st May 1993. The circular advises that a limited number of separate smoking rooms should be provided, where necessary, for staff and for patients who cannot stop smoking.

**7.11** No provision has been made in this Note for staff or patients who wish to smoke.

## Environment and design

### General

**7.12** Designers should create an environment that will help patients feel at ease, be conducive to efficient working, and contribute to staff morale. Particular note should be taken of 'Health Buildings in the Community' by NHS Estates, but reference should also be made to 'Better by Design' and 'Environments for quality care' also by NHS Estates, and 'Demonstrably Different' and 'First impressions, lasting quality', by the Department of Health.

**7.13** External landscaping is often of special value. The design process should also include the choice of well-designed furniture and fittings and coordination of carpets and colour.

### Disabled people

**7.14** It is essential to ensure that suitable access and facilities are provided for people who have problems of mobility or orientation or other special needs. This category includes, besides people who are wheelchair-bound, those who for any reason have difficulty in walking, and those with a sensory handicap such as visual or hearing impairment. Project teams are reminded of the need to comply with the provisions of:

a. The Chronically Sick and Disabled Persons Act 1970;

b. The Chronically Sick and Disabled Persons (Amendment) Act 1976;

c. The Disabled Persons Act 1981;

d. The Disabled Persons (Services, Consultation and Representation) Act 1986;

e. Department of the Environment Approved Document M (1992) to The Building Regulations 1991.

f. The Disability Discrimination Act 1995.

**7.15** Attention is drawn to BS5810: 1979 'Code of Practice for Access for the Disabled to Buildings' (under review). One of the effects of the 1981 Act is to apply this British Standard to premises covered by the 1970 Act, which includes those open to the public. Practical guidance for complying with The Building Regulations is issued by the Department of the Environment under Approved Document M: 'Access and facilities for disabled people'.

**7.16** Project teams should refer to HFN 14 – 'Disability access' and to HBN 40 – 'Common activity spaces' – a set of four volumes which includes guidance and Ergonomic Data Sheets on access, space and equipment relating to disabled users of health buildings.

**7.17** It is recommended that project teams consult local representatives of disabled people, or the Centre for Accessible Environments, with regard to the planning of spaces used by patients and escorts.

**7.18** In locations where public telephones are provided, one should be mounted at a height suitable for use by a person in a wheelchair and the handset fitted with an inductive coupler to assist any person using a hearing aid. See also HBN 48 – 'Telephone services'.

### Art in health buildings

**7.19** Works of art and craft can make a significant contribution towards the required standard of waiting areas in pharmacies. This need not be limited to the conventional hanging of pictures on a wall: murals, prints, photographs, sculptures, decorative tiles, ceramics, textile hangings and furniture may all help to create a pleasant environment.

**7.20** Advice should be sought from experts on:

a. obtaining grants. In some cases, Regional Arts Boards or charitable trusts with a local interest may offer grants to add money within a capital scheme which is set aside for art or craft works. The Royal Society of Arts offers bursaries for collaborations between architects and artists;

b. obtaining sponsorship. Local industries may see an advantage in supporting an arts project as a way of reaching a wide, or particular, audience;

### Waste disposal

**7.21** All waste pharmaceutical products should be disposed of safely, in accordance with the Special Waste Regulations.

### Courtyards

**7.22** Courtyards enable more rooms to receive natural daylight and ventilation, and provide an outlook which

can compensate for the lack of a longer view. Ground-cover planting is preferred to grass as it is often more successful and is easier to maintain.

**7.23** Access for maintenance should be from a corridor so that pharmacy staff are not disturbed.

**7.24** Reference should be made to HBN 45, 'External works for health buildings', for more detailed guidance on this subject.

### Natural and artificial lighting

**7.25** Sunlight enhances colour and shape, and helps to make a room bright and cheerful. The harmful effects of solar glare can be dealt with by architectural detailing of window shape and depth of reveals, as well as by installing external and internal blinds and curtains.

**7.26** Wherever possible, spaces to be occupied by patients, escorts or staff should have natural daylight with an outside view.

**7.27** Artificial lighting, as well as providing levels of illumination to suit activities, can make an important contribution to interior design. Designers should develop a lighting scheme that will help to promote a high quality image of the services being offered and a non-clinical, soft environment in as many spaces as possible. Levels of artificial light can also easily be varied by the use of dimmer switches.

**7.28** Fluorescent lighting in all areas where medicines or containers are processed should have suitable colour rendering characteristics. Lighting should be located to illuminate task areas without casting shadows. For further guidance on lighting refer to paragraph 8.66.

### Telephones

**7.29** Telephones should be provided in accordance with the needs of the department. Consideration should be given to the installation of a telephone system which will enable any incoming calls to be intercepted at an appropriate location – for example, the secretarial office.

**7.30** Unnecessary or abortive staff movement can be reduced by the provision of an intercommunication system; this should utilise the standard telephone network, be simple to use, and cover all locations of high staff activity. Such a system can accommodate a wide range of functions, both routine and emergency, and can enable staff to communicate rapidly when they require assistance. The facility can be used to contact another department easily and quickly, or to locate a member of staff elsewhere in the department.

**7.31** Public telephones will be required for the use of patients, their escorts and visitors, preferably in a convenient and accessible location in, or near to, the waiting area (see paragraph 4.45). Reference should be made to paragraph 7.18 above with regard to the provision of public telephones for disabled people. Further guidance is contained in HBN 48 – 'Telephone services' and HTM 2055 – 'Telecommunications'.

## Internal environmental engineering considerations

### Internal rooms

**7.32** Internal rooms may contribute to economy in planning. If, however, additional artificial lighting and ventilation are required, both capital and running costs are likely to be increased.

**7.33** Use of internal rooms should be limited to activities which:

a. need a controlled environment; or

b. are carried out intermittently by different individuals – for example, circulation areas and some storage areas.

**7.34** Rooms that are likely to be occupied for any length of time by a patient, an escort or a member of staff should have natural light.

### Ventilation

**7.35** Natural ventilation is preferred unless there are internal spaces or clinical reasons that call for mechanical ventilation or comfort-cooling systems.

**7.36** Mechanical ventilation and comfort-cooling systems are expensive in terms of capital and running costs; planning solutions should be sought which take maximum advantage of natural ventilation. Mechanical ventilation costs can be minimised by ensuring that, wherever practicable, core areas are reserved for rooms whose function requires mechanical ventilation irrespective of whether their location is internal or peripheral (for example, sanitary facilities).

### Noise and sound attenuation

**7.37** Any unwanted sound is a noise and may disturb patients and staff. Noise-sensitive areas should be located as remotely as possible from internal and external sources of unavoidable noise.

**7.38** Speech privacy is essential in spaces where personal and confidential discussions are held, such as the interview room; it should not be possible to overhear any discussions taking place in adjoining spaces.

**7.39** Particular care should be taken where the adjoining spaces are waiting areas.

**7.40** Sound transmission can be reduced by use of sound-attenuating partitions and doors, where appropriate. Use of soft floor-coverings, provision of curtains and acoustic treatment of walls and ceilings (where hygienically acceptable) will improve sound absorption in a space.

## Fittings and finishes

### General

**7.41** The quality of finishes in all areas should be of a high standard; the cost allowance makes due recognition of this need. Guidance on the selection of finishes is provided in the relevant Health Technical Memoranda (HTMs).

**7.42** Finishes should be robust enough to withstand accidental impact, and additional protection should be provided at likely points of contact. Trolleys and items of mobile equipment which may cause damage should be appropriately buffered.

### Dispensary

**7.43** All working surfaces, cupboards and shelves in dispensing and preparation areas must be finished with a smooth, impervious and washable material. Walls, floors and ceilings must be kept clean and a regular cleaning schedule maintained to ensure minimal cross infection and contamination.

### Sterile manufacturing – clean area

**7.44** The whole fabric of the clean area should be smooth, impervious, easily cleaned and able to withstand the repeated application of disinfectants. There should be no ledges where dust can collect and the angles – wall to ceiling, wall to floor and wall to work surface – should be flush-coved.

**7.45** The floor should be of a sealed construction such as terrazzo or welded polymer sheet with any welds being flat and level. There should be no drains for the removal of surface water since they present a microbial hazard. Cleaning is best undertaken by wet/dry vacuuming.

**7.46** Walls should meet the basic specification above and should be chip-resistant, particularly on corners. The surface should be even, with installations flush and sealed or in a flush-coved mounting plate sealed with a suitable silicon rubber sealant. If the wall is not sealed by a welded sheet or polymer it should be painted to a hard flat finish with a suitable resin-curing paint.

**7.47** Ceilings should be smooth, impervious and sealed in a manner comparable to that for the walls.

**7.48** Working surfaces should be cantilevered, coved and sealed directly into the wall, with the protruding edge also coved.

### Colour

**7.49** Decor colours should be light and pleasant. The colours chosen for the walls, floors and ceilings in areas where medicines or containers are processed should be compatible with the colour rendering properties of the lighting.

### Floors

**7.50** Floor coverings and skirting in the waiting area and counselling room should contribute to the provision of a non-clinical environment, yet at the same time, be hardwearing. They must not present a hazard to disabled people, nor should they restrict the movement of wheeled equipment. Floors in these areas should not be (nor appear to be) slippery, and the floor patterning should not induce disorientation. Changes of floor level should be avoided wherever possible. Surface drag, static electricity, flammability, infection hazards and impermeability to fluids have also to be considered. HTM 61, 'Flooring', should be consulted for advice on user requirements and performance selection.

**7.51** Finishes should be appropriate for the activities to be carried out, restricted in variety for ease of cleaning, and compatible with agreed cleaning routines.

### Doors and frames

**7.52** Doors and frames are particularly liable to damage from mobile equipment, and materials which will withstand this should be used. All double swing-doors should incorporate clear glass vision panels, but privacy, safety or other considerations may require that the panels should be capable of being obscured. Where necessary, doors should be capable of being fastened in the "open" position. Magnetic door retainers should not restrict the movement of traffic. Reference should be made to HTM 58 'Internal doorsets'.

*Sterile manufacturing – clean area*

**7.53** Doors should conform with the basic standard of finishes in this area. They should fit closely into their frames to maintain air pressures; open towards the higher pressure area; be self-closing; have no latches; be fitted with vision panels (except in changing rooms); and be so placed as to make transit as safe as possible. Sliding doors which can create uncleanable recesses are not acceptable. An indicator warning system is recommended to avoid doors at either end of an airlock being opened together. Pass through hatches should observe similar criteria, including the retention of air pressure by interlocks.

## Windows

**7.54** In addition to the various statutory requirements, the following aspects require consideration: illumination and ventilation; insulation against noise; user comfort; energy conservation; the prevention of glare; the provision of a visual link with the outside world. Windows should have a pleasant outlook if possible.

**7.55** Design should ensure that it is possible for cleaners to have easy access to the inside and outside of windows. Guidance on types of windows and on the safety aspects is available in HTM 55, 'Windows'.

*Sterile manufacturing – clean area*

**7.56** If external windows cannot have a northern aspect any measures taken to combat solar gain must not be allowed to intrude within the room.

**7.57** Supervision panels in all the internal rooms must be non-opening and without sills and their surface flush to the wall on the clean side: thus double glazing will be needed in some situations.

## Maintenance and cleaning

**7.58** Materials and finishes should be selected to minimise maintenance and be compatible with their intended function. Building elements that require frequent redecoration or are difficult to service or clean should be avoided. Special design consideration should be given to corners, partitions, counters and other elements which may be subjected to heavy use. Wall coverings should be chosen with cleaning in mind. Guidance on these aspects is given in HTM 56, 'Partitions', HTM 58, 'Internal doorsets', HTM 61, 'Flooring' and HTM 69, 'Protection'.

**7.59** In liaison with local authorities, consideration may need to be given to the provision of a dedicated bin store.

# 8.0 Engineering services

## Introduction

**8.1** This chapter describes the engineering services contained within a pharmaceutical department and how they integrate with the engineering systems serving the whole site. The guidance should acquaint the engineering members of the multi-disciplinary design team with the criteria and material specification needed to meet the functional requirements.

## Pharmaceutical requirements

**8.2** Whilst the requirements for heating, lighting and power installation in this department will not differ significantly from the conventional the application of the Medicines Act to hospital pharmacies will have an influence on four aspects of the engineering design, namely the provision of:

i. an adequate supply of quality monitored distilled water:

ii. a controlled environment in areas used for the preparation of sterile products;

iii. contained workstations for operator and/or product protection;

iv. facilities for product sterilization.

## Model specifications

**8.3** The NHS Estates Model Engineering Specifications, including the Scotland and Northern Ireland supplements, are sufficiently flexible to reflect local needs. The cost allowance is based on the quality of material and workmanship described in the relevant parts of the specifications.

## Economy

**8.4** Engineering services are a significant proportion of the capital cost and remain a continuing charge on revenue budgets. The project design engineer should therefore ensure:

- economy in initial provision, consistent with meeting functional requirements and maintaining clinical standards;
- optimum benefit from the total financial resources these services are likely to absorb during their lifetime.

**8.5** Where various design solutions are available, the consequential capital and running costs should be compared using the discounting techniques described in the Capital Investment Manual.

**8.6** The economic appraisal of various locations and design solutions should include the heat conversion and distribution losses to the point of use. Where buildings are located remote from the development's load centre, these losses can be significant.

**8.7** The energy management and accounting system should be part of the hospital building management system (BMS) and this should also include metering of all services where practical. If a hospital BMS is not available, the energy management and accounting system for this department should stand alone. It should also be suitable for subsequent integration with a future BMS. Further detailed guidance is contained in HTM 2005 – 'Building management systems'.

**8.8** In view of the increasing cost of energy, the project team should consider the economic viability of heat recovery and combined heat and power systems (CHP). Further guidance on CHP can be found in `A strategic guide to combined heat and power.' Designers should ensure that those services which use energy should do so efficiently and are metered where practicable.

## Maximum demands

**8.9** The estimated maximum demand and storage requirement, where appropriate, for each engineering service, will need to be assessed individually to take account of the size, shape, geographical location, operational policies and intensity of use of the department. NHS Estates may provide estimates of the maximum demand and storage requirements for a specific project if required by the project team.

## Activity Data

**8.10** Environmental and engineering technical data and equipment details are described in the Activity Data Sheets (see Chapter 10). They should be referred to for space temperatures, lighting levels, outlets for power, telephones, equipment details, etc.

## Safety

**8.11** The Health and Safety at Work etc Act 1974, as partly amended by the Consumer Protection Act 1987, together with the Workplace Regulations and the Work Equipment Regulations, and the Construction (Design and Management) Regulations 1994 impose statutory duties on

employers and designers to minimise – so far as reasonably practicable – any risks arising from the design, construction, use, cleaning or maintenance of engineering systems. One of the requirements of this legislation is to ensure, so far as is reasonably practicable, that design and construction is such that articles and equipment will be safe and without risks to health at all times when it is being set, used, cleaned or maintained by a person at work.

## Fire safety

**8.12** The project team should familiarise themselves with Firecode which contains the Department's policy and technical guidance on fire safety in hospitals and other NHS premises. In addition, the Fire Practice Note series provides guidance on specialist aspects of fire precautions.

**8.13** The Fire Precautions Act 1971 will apply to manufacturing premises and a fire certificate from the local fire authority may be required.

## Noise

**8.14** Excessive noise and vibration from engineering services, whether generated internally or externally and transmitted to individual areas, or noise from other sources, for example, speech which can be transmitted by the ventilation system, can adversely affect the operational efficiency of the department and cause discomfort to patients and staff. The limits and means of control advocated in HTM 2045 – 'Acoustics' should provide an acceptable acoustic environment.

**8.15** In addition to designing for control of noise levels, there may also be a need to ensure speech privacy, so that confidential conversations are unintelligible in adjoining rooms or spaces.

## Space for plant and services

**8.16** Space for plant and services should provide:

- easy and safe means of access, protected as far as possible from unauthorised entry;
- for frequent inspection and maintenance. Sufficient access panels should be provided for this purpose;
- for eventual removal and replacement of plant.

**8.17** Recommended spatial requirements for mechanical, electrical and public health engineering services are contained in HTM 2023 – 'Accommodation for plant and services'. HTM 2023 also refers to the Construction (Design and Management) Regulations.

**8.18** The distribution of mechanical and electrical services to final points of use should, wherever possible, be concealed in walls and above ceilings.

**8.19** Heat emitters should be contained within a 200mm wide perimeter zone under window sills and critical dimensions should be taken from the boundary of this zone.

**8.20** The 200mm zone includes the floor area occupied by minor vertical engineering ducts and is included in the building circulation allowance.

**8.21** Services contained in the space above the false ceiling, with the exception of drainage, should be confined to those required for the department.

## Access to control and isolation devices

**8.22** Devices for control and safe isolation of engineering services should be:

- located in circulation rather than working areas;
- protected against unauthorised operation;
- clearly visible and accessible, where intended for operation by the department's staff.

## Engineering commissioning

**8.23** The engineering services should be commissioned in accordance with the validation and verification methods identified in the latest HTMs. Engineering services for which a specific HTM is not currently available should be commissioned in accordance with `Engineering commissioning' published by the Institute of Healthcare Engineering and Estate Management. Flow measurement and proportional balancing of air and water systems require adequate test facilities to be incorporated at the design stage. Guidance is also contained in a series of commissioning codes published by the Chartered Institute of Building Services Engineers.

# MECHANICAL SERVICES

## Heating

**8.24** Except in clean and aseptic areas, spaces heated by low pressure hot water systems should use radiators of the low surface temperature type. Surface temperatures should not exceed 43°C. Exposed hot water pipe work, accessible to touch, should be insulated. Further guidance is contained in Health Guidance Note – "Safe" hot water and surface temperatures'.

**8.25** Radiators should normally be located under windows or against exposed walls with sufficient clear space between the top of the radiator and the window sill to prevent curtains reducing the output. There should be adequate space underneath to allow cleaning machinery to be used. Where a radiator is located on an external wall, back insulation should be provided to reduce the rate of heat transmission through the building fabric.

**8.26** It is recommended that radiators are fitted with thermostatic radiator valves. These should be of robust construction and selected to match the temperature and pressure characteristics of the heating system. The thermostatic head, incorporating a tamper-proof facility for pre-setting the maximum room temperature, should be controlled via a sensor located integrally or remotely as appropriate. To provide frost protection at its minimum setting, the valve should not remain closed below a fixed temperature.

**8.27** Radiators may also be used to offset building fabric heat loss in mechanically ventilated spaces.

**8.28** Flow temperatures to heating appliances should be controlled by the BMS in accordance with space requirements and external temperatures. The system should be zoned to suit the building.

## Ventilation (General)

**8.29** Air movement induced by mechanical ventilation should be from clean to dirty areas, where these can be defined. The design should allow for adequate flow of air into any space having only mechanical extract ventilation, via transfer grilles in doors or walls. Such arrangements, however, should avoid the introduction of untempered air and should not prejudice the requirements of fire safety or privacy.

**8.30** Mechanical ventilation should ensure that both supply and extract systems are in balance, and take account of infiltration as appropriate.

**8.31** Fresh air should be introduced via a low velocity system and should be tempered and filtered before being distributed via high level outlets. Diffusers and grilles should be located to achieve uniform air distribution within the space, without causing discomfort to patients.

**8.32** A separate extract system will be required for "dirty" areas, for example, toilet facilities. It should operate continuously throughout the day and night. A dual motor fan unit with an automatic changeover facility should be provided.

**8.33** External discharge arrangements for extract systems should be protected against back pressure from adverse wind effects and should be located to avoid reintroduction of exhausted air into this or adjacent buildings through air intakes and windows.

**8.34** Further detailed guidance is contained in the 'Design considerations' volume of HTM 2025 – 'Ventilation in healthcare premises'.

## Fume cupboards

**8.35** The factors which affect the performance of fume cupboards include an adequate supply air and effective exhaust system that allows the safe dispersal of waste products to atmosphere. The air velocity through sash openings must be sufficient to prevent hazardous materials from entering the laboratory whilst avoiding excessive flow rates that interfere with the investigation in progress. The design velocity must be maintained irrespective of whether the sash opening is varied or whether doors and windows are open or closed. Further detailed guidance concerning the selection and installation of fume cupboards is given in Health Equipment Information No 86.

## Extract canopies

**8.36** Extract canopies will be required over steam and heat-emitting equipment, that is sterilizers and container washing equipment and also over benches used for mixing, sifting and blending procedures. The airflow rate must be sufficient to ensure an adequate capture velocity in the vicinity of the process and a compact arrangement of equipment (but with access for maintenance) will minimise the canopy area and hence reduce the air volume necessary to achieve the optimum capture velocity.

## Ventilation in clean and aseptic areas

**8.37** Detailed information concerning environmental conditions can be found in 'Rules and Guidance for pharmaceutical manufacturers', 'The quality assurance of aseptic preparation services', BS 5295 and BS 5726. General information is also available in HEI 67 with regard to the selection and installation of laminar flow workstations with further detailed information concerning selection and installation of fume cupboards in HEI 86 and (for cytotoxic drugs) in HSE Guidance Note MS21.

**8.38** The design parameters for ventilation systems in these areas will include elimination of particulates shed by operatives, internal heat gains, room pressure differentials and the minimum number of air changes recommended in the standards. Protective and often restrictive clothing and head gear will be worn and therefore operator comfort is also an important consideration.

**8.39** The preparation of radiopharmaceutical products should be undertaken in a dedicated cabinet housed in a separate designated area. Each protective cabinet must have its own individual exhaust system incorporating effective precautions against blow-back and providing safe dispersal to atmosphere.

**8.40** Air extracted from areas where radioactive products are handled should not be recirculated. To cope with the risk of an accident or spillage outside safety cabinets, a panic button should be provided. Its function is to switch off the air supply to that space whilst providing extract only. The controls should provide for all air extracted from the department under these circumstances to be discharged to atmosphere. The Health and Safety Executive's requirements in these areas must be consulted at the design stage of all projects.

**8.41** The ventilation systems in clean and aseptic areas and the airflow through protective cabinets should be designed for continuous operation and should only be shut down for the purposes of maintenance or emergency isolation. Protective cabinets should be provided with a visual indication of airflow and with the minimum safe airflow clearly shown. There should also be an audible and visual warning if the flow falls below the safe level or if the general ventilation supply or extract fans fail.

**8.42** Supply and extract ventilation systems should include local controls and indicator lamps to confirm the operational status of each system. Where the system is used on a regular daily pattern, timeswitch control with manual override for a limited period should be considered. The indicators for a system serving a particular space should be in or immediately adjacent to that space. It may be appropriate to locate all indicators at the staff base. Where manual controls are available for staff use, they should be provided with labels which clearly define their function.

## Heat recovery

**8.43** As part of a whole hospital energy strategy consideration should be given to the recovery of heat extracted from the department where this is economic and where no toxic or corrosive substances are carried in the extract air. Although substantial energy expenditure is incurred in tempering air exhausted through fume cupboards and protective cabinets heat reclamation should not compromise laboratory ventilation requirements or the free flow of air through enclosures.

**8.44** Condenser cooling water used in the distillation process should be utilised to preheat domestic hot water services where it is convenient and economic to do so.

## Ventilation (substances hazardous to health)

**8.45** Local exhaust ventilation will be required where exposure by inhalation of substances hazardous to health cannot be controlled by other means. The Health and Safety Executive in their current publication EH40, Occupational Exposure Limits, updated annually, sets limits which form part of the Control of Substances Hazardous to Health Regulations 1994 (COSHH).

## Hot and cold water services

**8.46** Guidance on the design and installation of hot and cold water supply and distribution systems is contained in HTM 2027 – 'Hot and cold water supply, storage and mains services'.

**8.47** All cold water pipework, valves and fittings should be economically insulated and vapour sealed to protect against frost, surface condensation and heat gain.

**8.48** The domestic hot water supply should be taken from the general hospital calorifier installation at a minimum outflow temperature of 60°C ± 2.5°C and distributed to all outlets such that the return temperature at the calorifier is not less than 50°C. See Health Guidance Note – '"Safe" hot water and surface temperatures'.

**8.49** The requirements for the control of legionellae bacteria in hot and cold water systems are set out in HTM 2040 – 'The control of legionellae in health care premises – a code of practice'.

**8.50** In dispensing areas, outlets should be fitted with bottle filling nozzles or hose connections located over the centre of sinks at a minimum clearance height of 550 mm and should incorporate precautions against back siphonage.

**8.51** The cold water supply for dispensing purposes and to distillation plant should be taken direct from the supply undertaking's mains. Where fully potable cold water systems are not provided, a drinking water tap should be provided in the toilets and the staff room. The supply to these should be direct from the mains or from a protected tank.

## Distilled water

**8.52** Distillation is the recommended purification process to remove any bacteria viruses and pyrogens contained in raw mains feedwater. Pre-treatment of water in hard water areas will be required. As previously referred to in paragraph 5.14 distilled water will be required in quantity for product preparation in sterile and non-sterile areas

and also for cleaning purposes eg bottle washing. Plant capacity will depend upon local aggregate demand for freshly distilled water and that drawn from temperature controlled storage but a diversity rate in the range 50-150 litres/hour with a storage capacity of 100-300 litres will normally be adequate. Plant and distribution pipework should be robust, inert and easily maintained. For sterile manufacturing a recirculatory system is recommended with duplicate pumps to ensure continuous operation. Instrumentation should include facilities for recording distillate temperature, flow and conductivity.

**8.53** The production of purified water by condensing steam from a hospital central steam generation plant is not recommended. It has the disadvantage that chemicals used for raw feed water treatment together with inhibitors and possibly oil are potential contaminants that could be carried over to the distilled water circuit.

## Steam supply

**8.54** Further information on steam supplies can be obtained in HTM 2010 – 'Sterilization' and HTM 2031 – 'Clean steam'.

## Sterilizers

**8.55** Detailed guidance concerning the selection, installation and commissioning of bottled fluids sterilizers and electrically heated sterilizing ovens (hot air sterilizers) is given in HTM 2010. Whilst the scale of provision will be variable and influenced by local factors eg scale of manufacturing operation, clinical specialties served etc, continuity of production is important. Selection of type and capacity of sterilizing equipment should therefore include sufficient diversity to enable a standby service to be maintained.

## Flammable stores

**8.56** In addition to the general guidance given in HTM 83, HS(G) 51 deals specifically with the requirements for the safe storage of flammable liquids.

## Piped medical gases and vacuum

**8.57** Guidance on piped medical gas systems and gas storage is contained in HTM 2022 – 'Medical gas pipeline systems'.

## Pneumatic tube transport

**8.58** Pneumatic tube transport may provide a viable alternative to porters for moving drugs and other products to and from the pharmacy. Further guidance on pneumatic conveyor systems is contained in HTM 2009 – 'Pneumatic air tube transport systems'.

# ELECTRICAL SERVICES

## Electrical installation

**8.59** The installation should comply in all respects with BS7671 – `Requirements for Electrical Installations'. IEE Wiring Regulations. 16th Edition (and subsequent amendments) and HTM 2007 – 'Electrical services: supply and distribution'.

**8.60** The point of entry for the electrical supply should be a switch cupboard housing the main isolators and distribution equipment. This space will also be the distribution centre for subsidiary electrical services. Supplies should be metered and, whenever possible, equipment should be mounted at a height which gives easy access from a standing position. Switchgear should be lockable in the "off" position.

**8.61** The electrical equipment in occupied areas should generally be concealed using PVC-insulated cable and screwed steel conduit or trunking; however in certain circumstances mineral insulated metal-sheathed or steel wire armour (SWA) cables may be used. External installations should use PVC-insulated cables in galvanised screwed steel conduit with waterproof fittings.

## Electrical interference

**8.62** Care should be taken to avoid mains-borne interference, electrical radio frequency and telephone interference affecting computers and other electronic equipment used here or elsewhere on the site.

**8.63** Electrical products, systems and installations should not cause, or be unduly affected by electromagnetic interference. This requirement is in the form of an EC Directive on Electromagnetic Compatibility (89/336/EEC as amended by 91/263/EEC and 92/31/EEC). This Directive has been implemented in UK law by the Electromagnetic Compatibility Regulations 1992 (SI No 2372), which came into force on 28 October 1992.

**8.64** Guidance on the avoidance and abatement of electrical interference is contained in HTM 2014 – 'Abatement of electrical interference'.

**8.65** Fluorescent luminaires should comply with BS 5394.

## Lighting

**8.66** Colour finishes and lighting throughout the department should be co-ordinated to create a calm and welcoming atmosphere. Practical methods are contained in the CIBSE Lighting Guide LG2 – 'Hospitals and Health Care Buildings'.

**8.67** It is essential that fluorescent lighting in all areas where medicines or containers are processed, including stores, is derived from one of the recommended types of lamps having suitable colour rendering characteristics.

**8.68** Architects and engineers should collaborate to ensure that decorative finishes are compatible with the colour rendering properties of lamps and that the spectral distribution of the light sources is not adversely affected.

**8.69** Luminaires should be manufactured and tested in accordance with the requirements specified in the relevant sections of BS4533. Their location should afford ready access for lamp changing and maintenance, but with the overriding requirement that the recommended standard of illuminance is provided to the task area.

**8.70** In areas where there are fixed workbenches or externally located fume cupboards, luminaires should be located to illuminate task areas without casting shadows.

**8.71** Lighting switches in clean or aseptic areas should have front plates flush with the wall surface with no projecting ledges.

**8.72** In clean or aseptic areas, luminaires should be of the recessed type with the diffuser flush with the ceiling. The luminaires should be of the 'sealed' type and should be arranged to enable relamping from outside the area (that is, from the ceiling void above) if possible.

**8.73** The number and location of luminaires connected to a circuit and the number of switches and circuits provided should allow flexibility in the general and local level of illumination, particularly in areas away from windows where daylight can vary significantly. Some areas of the department, which may be unoccupied for long periods may also be suited to automatic/presence switching.

**8.74** Generally, energy-efficient luminaires should be used wherever possible. Intermittently and infrequently used luminaires may be fitted with compact fluorescent or incandescent lamps.

**8.75** Where visual display terminals (VDTs) are to be used, the lighting should be designed to avoid bright reflections on the screen and to ensure that the contents of the screen are legible and meet the Health and Safety (Display Screen Equipment) Regulations 1992, which came into force on 1 January 1993. The Regulations implement a European directive, No. 90/270/EEC of 29 May 1990, on minimum safety and health requirements for work and display screen equipment. Further guidance is contained in the CIBSE Lighting Guide LG3.

**8.76** The lighting of corridors, stairways and other circulation areas, which generally are areas not covered by Activity Data room data sheets, should be in accordance with the guidance contained in Volume 4 of HBN40/SHPN40 – 'Common activity spaces'.

**8.77** Safety lighting should be provided on primary escape routes in accordance with HTM 2011 – 'Emergency electrical services' and BS5266.

## Controlled Drugs cupboard

**8.78** A red indicating lamp should be provided on each Controlled Drugs cupboard and, where appropriate, outside the doorway to the room in which the cupboard is located and at a continuously staffed location. The lamps should be interlocked with the cupboard and alarm system to give visual and audible indication at the continuously staffed location of unauthorised entry to the cupboard.

**8.79** An indicating lamp denoting that the circuit is energised should also be fitted to each cupboard. The supply circuits for the lamps and alarm system should be derived from essential circuits. The cupboards should comply with BS2881. Further information is contained in HTM 63 – 'Fitted storage systems'. More general information is contained in HC(77) 16 (in Wales – WHN (77) 32) and guidelines for the Safe and Secure Handling of Medicines.

## Socket-outlets and power connections

**8.80** Sufficient 13 amp switched and shuttered socket-outlets, connected to ring, spur circuits, should be provided to supply all portable appliances used simultaneously. The installation of twin outlets should be considered where activities occur in juxtaposition.

**8.81** Switched socket outlets should be provided in corridors and in individual rooms to enable domestic cleaning appliances with flexible leads (9 metres long) to operate over the whole department.

**8.82** Appliances requiring a three-phase supply, or those rated in excess of 13 amp single phase, should be permanently connected to separate fused sub-circuits. The sub-circuits should be fed from the distribution board and terminate at a local isolator. Fixed appliances, less than 13 amp rating, should be permanently connected to a double-pole switched 13 amp spur outlet. The spur outlet should contain an indicating light, where appropriate, and a suitable fuse.

**8.83** Isolation switches should be provided adjacent to all engineering plant and equipment for use by maintenance staff.

**8.84** All socket-outlets within pharmaceutical manufacturing areas should be connected such that a supply is available from at least two separately fused circuits of the same phase.

**8.85** Socket outlets should be connected to essential circuits in accordance with the guidance contained in HTM 2011 – 'Emergency electrical services'.

**8.86** The electrical supply connections to all medical electrical equipment should comply with BS EN 60 601-1-2:1993.

## Emergency electrical supplies

**8.87** Guidance on emergency electrical supplies is contained in HTM 2011 – 'Emergency electrical services'.

## Main entrance security systems

**8.88** The main entrance should be controlled by a door security and/or closed-circuit television surveillance system which provides for verbal communication with, and an electro-magnetically operated door lock to be controlled from, the reception desk.

**8.89** Further guidance is contained in the NAHAT Security Manual.

## Personal alarm transmitters

**8.90** Local security policies should determine at the planning stage whether or not staff are to be issued with personal alarm transmitters. If personal alarm transmitters are not 'self contained' then conduits and accommodation for transmitting/receiving equipment and propagating devices, such as induction loops and/or aerials, will be required to suit the selected system.

## Security alarm

**8.91** A security alarm actuating switch or button should be located unobtrusively at the out-patient service counter. It should be connected to a continuously staffed area such as the hospital telephone switchboard on the porters' room.

## Telephones

**8.92** Central telephone facilities for internal and external calls will normally be available and should be extended to serve this department. Telephones will normally be of the desk pattern.

**8.93** Coin and/or card operated payphones and free phone for taxis, depending on local policy, should be provided in or adjacent to the dispensary waiting area.

**8.94** Self-contained intercommunication systems are relatively inflexible and limited in the extent of their economic application. Any subsequent modifications to them usually involve disproportionate cost. In only very rare instances can such systems be justified for functional or clinical reasons.

**8.95** A properly planned telephone system will provide prompt intercommunication facilities between all extensions. Abbreviated dialling can be used for a range of frequently called extension numbers. Consequently, reasons for providing a separate intercommunication system should be clearly shown.

**8.96** Further guidance on telephone systems is contained in HBN48 – 'Telephone services' and HTM 2055 – 'Telecommunications (telephone exchanges)'.

## Data links

**8.97** Conduits will be required for cables to interconnect electronic equipment. The extent to which these conduits should link all workstations in this department and the main hospital system or elsewhere will depend on the local policy for automatic data processing (see paragraph 2.24). If a structured cable system is to be installed within the hospital, then the pharmacy department should be provided with all outlets wired and connected (refer to HGN – 'Structured cabling for IT systems').

## Clocks

**8.98** Clocks may be of impulse, synchronous or battery/quartz type.

## Lightning protection

**8.99** Protection of the building against lightning should be provided in accordance with HTM 2007 and BS6651:1992.

## INTERNAL DRAINAGE

## General

**8.100** The primary objective is to provide an internal drainage system which:

- uses the minimum of pipework;
- remains water and air tight at joints and connectors;
- is sufficiently ventilated to retain the integrity of water seals.

## Design parameters

**8.101** The design should comply with the relevant British Standards and Codes of Practice, including BS5572, and the current building regulations. Recommendations for spatial and access requirements for public health engineering services are contained in HSE Data Sheet EA5.

**8.102** The gradient of branch drains should be uniform and adequate to convey the maximum discharge to the stack without blockage. Practical considerations, such as available angles of bends, junctions and their assembly, as well as space considerations, usually limit the minimum gradient to about 1:50 (20mm/m). For larger pipes, for example 100mm diameter, the gradient may be less, but this will require workmanship of a high standard if an adequate self-cleaning flow is to be maintained. It is not envisaged that pipes larger than 100mm diameter will be required within interfloor or ground floor systems serving this department.

**8.103** Provision for inspection, rodding and maintenance should ensure "full bore" access and be located to minimise disruption or possible contamination. Manholes should not be located within this department.

**8.104** The system should be designed to avoid the use of internal manholes, and access points for pipework cleaning should be located to minimise disturbance to staff in the event of a blockage.

**8.105** To prevent the ingress of bacteria the waste outlets from sterilizers, distillation plant, glassware washing machines and refrigerators should be connnected outside of the department, not be directly connected to the drainage system and discharge via a trapped tundish or gully.

**8.106** In situations where the effluent contains corrosive or toxic substances the local authority should be consulted before any connection is made to the main drainage system. The pipework materials should be carefully selected and be resistant to attack from the media being discharged and have a smooth internal finish.

# 9.0 Cost information

## Introduction

**9.1** For all types of health building, it is important that building costs and revenue expenditure are kept as low as possible and consistent with acceptable standards. In applying the guidance in this document to determine a detailed design, the need for economy should always be of prime concern and the activities should be carefully considered so that, where appropriate, space can be shared for similar activities which are programmed to take place at different times. The solution should not be detrimental to the proper functioning of the spaces involved nor to the needs of the users. Within this general context, Health Building Notes provide a synopsis of accommodation for health buildings which the Department of Health recommends for the provision of a given service.

## Departmental Cost Allowance Guides

**9.2** Departmental Cost Allowance Guides (DCAGs) related to this Note are officially notified in 'Quarterly Briefing' published by NHS Estates. A full listing of all DCAGs is listed in the DCAG Database – a hard copy of which together with some guidance notes can be obtained from NHS Estates. Further information on this can be obtained from NHS Estates, telephone (01132) extensions 547025, 547106 or 547030.

**9.3** The attention of the project team is drawn to guidance given in the Capital Investment Manual (Business Case Guide) published by The Stationery Office. This publication seeks to reflect the important changes that have taken place over recent years, both with the introduction of the NHS reforms and with the changing patterns of health care delivery. This process is intended to reduce unnecessary and often expensive planning work which may subsequently prove to be abortive and emphasises the necessity for a sound business case in support of the capital expenditure involved. The Capital Investment Manual also defines that the Capital Works estimate of the intended scheme must be based on, wherever applicable, industry norms such as the DCAGs plus a percentage to cover for on-costs.

**9.4** The DCAGs for this Note reflect the accommodation that the Pharmaceutical Services Department will require when incorporated into an acute general hospital where the common use of services will be available. Costs are based on the typical two-storey new-build, on a greenfield site standing in its own grounds with no planning constraints.

**9.5** The DCAGs for this Note also cover the building and engineering requirements. An allowance for on-costs (that is, external works, external engineering services and abnormals) should be added to the DCAGs for this department. The abnormals will largely be determined by the characteristics of the site, such as an inner-city location, or the condition and type of the existing building if refurbishment is the only option.

**9.6** It is also important that project teams assess at the earliest opportunity all the likely on-cost implications of individual sites and schemes.

**9.7** DCAGs are exclusive of VAT, Building and Planning Fees and all Local Authority charges and are based on a Locational Factor of 1.

## Locational Factors

**9.8** Locational factor adjustments may be applied to the Works Costs (that is the total of the DCAGs plus the requisite on-costs) to take into account the local market conditions. For further information regarding these please refer to the Regional Location factors in 'Quarterly Briefing' published by NHS Estates.

## Functional units

**9.9** The functional units for this note are as follows:

**Primary services**

In-patient dispensing service

- medium-sized hospital
- large-sized hospital

Aseptic dispensing suite

Out-patient service

- attached
- remote

Radiopharmaceuticals

**Pharmaceutical support services**

Sterile and non-sterile manufacturing

Assembly

Quality control

Purchase and distribution

The activity spaces and areas used for costing the functional units are listed in the schedules of accommodation at the end of this chapter.

**9.10** A schedule of accommodation for an aseptic dispensing suite is provided for pharmacy departments that do not have access to aseptic facilities in an on-site manufacturing unit. The schedule of accommodation for a manufacturing unit is based on a large facility serving a number of hospitals. The assembly unit need not necessarily be in the same location as the manufacturing unit.

## Essential complementary accommodation (ECA)

**9.11** This comprises activity spaces which are essential to the running of the unit, but which in certain circumstances may be available in a convenient location elsewhere. The amount of ECA which will need to be provided as part of an individual project will therefore vary according to the extent of the provision elsewhere. The ECA costed in this Note are listed in the schedules of accommodation at the end of this chapter.

**9.12** Included within the ECA accompanying this Note are hospital and regional drug information services. This accommodation is essential to the local/regional area, but is not necessarily an essential component of the Pharmaceutical Department provision.

## Optional accommodation and services (OAS)

**9.13** This Note, where appropriate, draws attention to project options for providing services or facilities, including the likely cost implications. This information will enable the project manager to select the solution which is most suitable to their needs. The OAS costed in this Note are listed in the schedules of accommodation at the end of this chapter.

## Dimensions and areas

**9.14** In determining spatial requirements, the essential factor is not the total area provided but the critical dimensions, that is, those dimensions critical to the efficient functioning of the activities which are to be carried out. To assist project teams in preparing detailed design solutions for the rooms and spaces, studies have been carried out to establish dimensional requirements in the form of critical dimensions. The results of these studies appear as ergonomic diagrams in Health Building Note 40 – Volumes 1-4.

**9.15** For development planning and at the earliest stage of a design, it may be convenient for designers to have data available which will enable them to make an approximate assessment of the sizes involved. For this reason, the areas prepared for the purpose of establishing the cost allowances are listed in the schedules of accommodation at the end of this chapter.

**9.16** It is emphasised that the areas published do not represent recommended sizes, nor are they to be regarded in any way as specific individual entitlements.

**9.17** Efficient planning of the building may also necessitate variation of areas. For instance, in the refurbishment or conversion of older property:

a. rooms tend to be larger than the recommended area

b. some rooms may be too small or in the wrong location for efficient use

c. circulation space tends to form a larger than normal proportion of the total area.

## Circulation

**9.18** Space for circulation, as well as including space for all corridors, also includes a five percent allowance for planning, a three percent addition for an engineering zone adjacent to the external walls, all small vertical ducts and spaces occupied by partitions and walls. These areas are all included and therefore costed in the DCAGs.

**9.19** It is also important to remember that the circulation figures included in the DCAGs for this Note are those anticipated for new purpose built premises with no constraints. Where constraints are encountered, for example in refurbishment or conversion of older types of property, this circulation figure would be likely to increase accordingly, therefore some adjustment may be necessary to the circulation figure.

## Communications

**9.20** Staircases and lifts are not included in the DCAGs relevant to this unit. Costs related to these elements along with a suitable space standard allowance should be made in the on-costs. For further reference please refer to HBN 40 – Volume 4 'Circulation areas'.

## Land costs

**9.21** As is the norm for DCAGs costs are exclusive of all land costs and associated fees. However, the project team's attention is drawn to the fact that costs associated with these should be included in the Business Case

Submission, all as detailed in the Capital Investment Manual, and could therefore be an important part of the overall cost viability of the scheme.

## Engineering services

**9.22** The following engineering services, as described in the Engineering Chapter and exemplified in the Activity Data, are included in the cost allowances. Primary engineering services are assumed to be conveniently available at the boundary of the unit.

**a. Mechanical services**

**Heating:** low pressure hot water system with thermostatic radiator control, maximum touch temperature 43oC.

**Ventilation:** mechanical supply and extract to meet clinical and functional requirements.

**Cold water service:** supplied from a central storage system to service points and includes drinking water and hose reels. Storage tanks are therefore not included.

**Hot water service:** supplied from a central storage system with thermostatic mixing valves (as appropriate) at outlets. Storage is not included.

**Treated water system**

**b. Electrical services**

**Departmental distribution switchboard.**

**Building management system.**

**Lighting system:** general lighting as required by tasks. Fluorescent, tungsten, safety and emergency luminaires as appropriate.

**Power system:** socket outlets and other power outlets for fixed and portable equipment.

**Standby and safety installation from the main hospital site.**

**Supplementary equipotential earth bonding.**

**Alarm system:** fire, security, medical gases and drug cupboard.

**Clocks (optional wired system)**.

**Telephone:** conduits, cabling and outlets, but excluding instruments (handsets, payphones etc).

**Data transmission:** conduits and socket outlets only.

**c. Equipment (Group 1)**

**Fume cupboards.**

**Controlled drugs cupboard.**

**Refrigerators.**

**Sterilizers.**

**Thermostatic mixing valves.**

## Schedules of accommodation

**9.23** The following schedules are based on the text in Chapters 4 and 5, and are illustrative of the acceptable accommodation for the functional units detailed.

**PRIMARY SERVICES**
**Schedule of Accommodation**

| Para. No | Activity | SPACE AREA m² | Medium size hospital Qty | TOTAL AREA m² | Large hospital Qty | TOTAL AREA m² |
|---|---|---|---|---|---|---|
| 4.01 | Dispensary | | 1 | 70.00 | 1 | 95.00 |
| 4.14 | Extemporaneous preparation | 7.50 | 1 | 7.50 | 1 | 7.50 |
| 4.16 | Ward service area | 33.50 | 1 | 33.50 | 1 | 33.50 |
| 4.23 | Ward box/trolley holding store | | 1 | 12.50 | 1 | 14.00 |
| 4.49 | Goods reception/unpacking area | 25.00 | 1 | 25.00 | 1 | 25.00 |
| 4.51 | General store | | 1 | 40.00 | 1 | 60.00 |
| 4.53 | Temperature controlled storage | | 1 | 12.50 | 1 | 20.00 |
| 4.57 | Secure store | 10.50 | 1 | 10.50 | 1 | 10.50 |
| 4.58 | Containers store | | 1 | 9.50 | 1 | 13.00 |
| 4.63 | Flammables store | 6.00 | 1 | 6.00 | 1 | 6.00 |
| 4.67 | Returned medicines store | 6.00 | 1 | 6.00 | 1 | 6.00 |
| 4.68 | Non-formulary drugs store store | 6.00 | 1 | 6.00 | 1 | 6.00 |
| 4.69 | Unlicensed drugs store store | 6.00 | 1 | 6.00 | 1 | 6.00 |
| 4.70 | Principal pharmacist's office | 9.00 | 1 | 9.00 | 1 | 9.00 |
| 4.71 | Pharmacists' office | | 1 | 11.00 | 1 | 15.00 |
| 4.72 | Clinical pharmacists' office | | 1 | 15.00 | 1 | 20.00 |
| 4.73 | Dispensing manager's office | 9.00 | 1 | 9.00 | 1 | 9.00 |
| 4.74 | Secretarial office | 9.00 | 1 | 9.00 | 1 | 9.00 |
| 4.75 | Clinical trials office | | 1 | 15.00 | 1 | 25.00 |
| 4.76 | Storekeeper's office | 7.00 | 1 | 7.00 | 1 | 7.00 |
| 4.77 | Porter's base | 5.00 | 1 | 5.00 | 1 | 5.00 |
| 4.83 | Staff W.C. | 2.00 | 2 | 4.00 | 3 | 6.00 |
| 4.84 | Staff rest room & beverage bay | | 1 | 15.00 | 1 | 20.00 |
| | NET TOTAL | | | 344.00 | | 427.50 |
| | Planning | 5% | | 17.20 | | 21.38 |
| | Sub - Total | | | 361.20 | | 448.88 |
| | Engineering zone | 3% | | 10.84 | | 13.47 |
| | Circulation | 22% | | 79.46 | | 98.75 |
| | GROSS TOTAL | | | 451.50 | | 561.09 |
| | **DEPARTMENTAL TOTAL** | | | **450.00** | | **560.00** |

## ASEPTIC DISPENSING SUITE
### Schedule of accommodation

| Para. No | Activity | SPACE AREA m² | Qty | TOTAL AREA m² |
|---|---|---|---|---|
| 4.25 | **Aseptic dispensing suite** | | | |
| 4.25 | Wash/change/robe room | 6.50 | 1 | 6.50 |
| 4.30 | Aseptic room | 7.50 | 1 | 7.50 |
| 4.36 | Support room | 11.00 | 1 | 11.00 |
| | NET TOTAL | | | 25.00 |
| | Planning | 5% | | 1.25 |
| | Sub - Total | | | 26.25 |
| | Engineering zone | 3% | | 0.79 |
| | Circulation | 24% | | 6.30 |
| | GROSS TOTAL | | | 33.34 |
| | **DEPARTMENTAL TOTAL** | | | **35.00** |

## OUT-PATIENT SERVICES
### Schedule of Accommodation

| Para. No | Activity | SPACE AREA m² | attached Qty | attached TOTAL AREA m² | remote Qty | remote TOTAL AREA m² |
|---|---|---|---|---|---|---|
| 4.40 | Out-patient service counter | 12.00 | 1 | 12.00 | 1 | 12.00 |
| 4.44 | Waiting area | 16.00 | 1 | 16.00 | 1 | 16.00 |
| 4.47 | Interview room | 6.00 | 1 | 6.00 | 1 | 6.00 |
| 4.01 | Out-patient dispensary | 34.00 | | | 1 | 34.00 |
| | NET TOTAL | | | 34.00 | | 68.00 |
| | Planning | 5% | | 1.70 | | 3.40 |
| | Sub - Total | | | 35.70 | | 71.40 |
| | Engineering zone | 3% | | 1.07 | | 2.14 |
| | Circulation | 13% | | 4.64 | | 9.28 |
| | GROSS TOTAL | | | 41.41 | | 82.82 |
| | **DEPARTMENTAL TOTAL** | | | **40.00** | | **85.00** |

## SUPPORT SERVICES
## Schedule of Accommodation - Manufacturing Services

| Para. No | Activity | SPACE AREA $m^2$ | Qty | TOTAL AREA $m^2$ |
|---|---|---|---|---|
| | **Sterile manufacturing** | | | |
| 5.01 | Ingredients weighing room | 7.00 | 1 | 7.00 |
| 5.02 | Container unpacking & preparation | 31.00 | 1 | 31.00 |
| 5.05 | Clean Area | | | |
| 5.08 | Preparation room | 26.00 | 1 | 26.00 |
| 5.09 | Cleaning bay | 5.00 | 1 | 5.00 |
| 5.11 | Filling room | 17.50 | 1 | 17.50 |
| 5.12 | Aseptic room | 7.50 | 1 | 7.50 |
| 5.14 | Still room | 6.50 | 1 | 6.50 |
| 5.15 | Wash/change/robe room | 8.50 | 1 | 8.50 |
| 5.16 | Aseptic wash/robe changing room | 5.00 | 1 | 5.00 |
| 5.17 | Cleaner's room | 7.00 | 1 | 7.00 |
| 5.19 | Sterilization loading/cooling area | 35.50 | 1 | 35.50 |
| 5.22 | Inspection and labelling area | 28.00 | 1 | 28.00 |
| | **Non-sterile manufacturing** | | | |
| 5.23 | Ingredients weighing room | 11.00 | 1 | 11.00 |
| 5.24 | Container unpacking & preparation | 37.00 | 1 | 37.00 |
| 5.26 | Changing room | 7.00 | 1 | 7.00 |
| 5.27 | Dry & liquid products area | 40.00 | 1 | 40.00 |
| 5.30 | Creams and ointments room | 30.00 | 1 | 30.00 |
| 5.32 | Hazardous dry products room | 8.00 | 1 | 8.00 |
| 5.33 | Flammable materials room | 15.00 | 1 | 15.00 |
| 5.34 | Cleaning bay | 7.00 | 1 | 7.00 |
| 5.35 | Bulk liquid filling area | 15.00 | 1 | 15.00 |
| 5.36 | Inspection and labelling area | 28.00 | 1 | 28.00 |
| | **Manufacturing Stores** | | | |
| 5.37 | Quarantine store | 109.00 | 1 | 109.00 |
| 5.39 | Materials store | 49.50 | 1 | 49.50 |
| 5.40 | Consumables/equipment store | 20.00 | 1 | 20.00 |
| 5.41 | Containers store | 49.50 | 1 | 49.50 |
| 5.42 | Finished products store | 116.00 | 1 | 116.00 |
| | **Manufacturing Support Spaces** | | | |
| 5.45 | Pharmacist's office | 9.00 | 1 | 9.00 |
| 5.45 | Cleaner's room | 7.00 | 1 | 7.00 |
| 5.45 | Staff changing | 10.00 | 2 | 20.00 |
| 5.45 | Staff W.C. | 2.00 | 4 | 8.00 |
| 5.45 | Staff room & beverage bay | 22.50 | 1 | 22.50 |
| | Switchroom | 4.00 | 1 | 4.00 |
| | NET TOTAL | | | 797.00 |
| | Planning | 5% | | 39.85 |
| | Sub - Total | | | 836.85 |
| | Engineering zone | 3% | | 25.11 |
| | Circulation | 22% | | 184.11 |
| | GROSS TOTAL | | | 1,046.06 |
| | **DEPARTMENTAL TOTAL** | | | **1,045.00** |

## SUPPORT SERVICES
## Schedule of Accommodation - Assembly

| Para. No | Activity | SPACE AREA $m^2$ | Qty | TOTAL AREA $m^2$ |
|---|---|---|---|---|
| | **Assembly** | | | |
| 5.47 | Container preparation area | 15.00 | 1 | 15.00 |
| 5.48 | Unpacking area | 10.00 | 1 | 10.00 |
| 5.49 | Tablet packing area | 9.50 | 1 | 9.50 |
| 5.50 | Liquid filling area | 10.00 | 1 | 10.00 |
| 5.51 | Creams and ointments area | 10.00 | 1 | 10.00 |
| 5.52 | Flammable materials area | 15.00 | 1 | 15.00 |
| 5.53 | Visual inspection & labelling area | 15.00 | 1 | 15.00 |
| 5.54 | Equipment cleaning room | 8.50 | 1 | 8.50 |
| 5.55 | Materials store | 7.50 | 1 | 7.50 |
| 5.55 | Clean equipment store | 6.50 | 1 | 6.50 |
| 5.55 | Containers store | 15.00 | 1 | 15.00 |
| 5.55 | Packed products store | 11.50 | 1 | 11.50 |
| | NET TOTAL | | | 133.50 |
| | Planning | 5% | | 6.68 |
| | Sub - Total | | | 140.18 |
| | Engineering zone | 3% | | 4.21 |
| | Circulation | 22% | | 30.84 |
| | GROSS TOTAL | | | 175.22 |
| | **DEPARTMENTAL TOTAL** | | | **175.00** |

## SUPPORT SERVICES
## Schedule of Accommodation - Quality Control

| Para. No | Activity | SPACE AREA $m^2$ | Qty | TOTAL AREA $m^2$ |
|---|---|---|---|---|
| | **Quality control** | | | |
| 5.63 | Chemical testing laboratory | 51.00 | 1 | 51.00 |
| 5.68 | Instrument laboratory | 43.00 | 1 | 43.00 |
| 5.72 | Weighing area | 5.00 | 1 | 5.00 |
| 5.77 | Reference sample store | 7.50 | 1 | 7.50 |
| 5.78 | Pharmacist's office/sample reception | 20.00 | 1 | 20.00 |
| | NET TOTAL | | | 126.50 |
| | Planning | 5% | | 6.33 |
| | Sub - Total | | | 132.83 |
| | Engineering zone | 3% | | 3.98 |
| | Circulation | 22% | | 29.22 |
| | GROSS TOTAL | | | 166.03 |
| | **DEPARTMENTAL TOTAL** | | | **165.00** |

## SUPPORT SERVICES
## Schedule of Accommodation - Purchase & Distribution

| Para. No | Activity | SPACE AREA m² | Qty | TOTAL AREA m² |
|---|---|---|---|---|
| | **Purchase & distribution service** | | | |
| 5.81 | External goods entrance | 36.00 | 1 | 36.00 |
| 5.82 | Goods reception and unpacking area | 18.00 | 1 | 18.00 |
| 5.84 | Despatch assembly area | 36.50 | 1 | 36.50 |
| 5.87 | Refuse collection area | 25.00 | 1 | 25.00 |
| 5.88 | General Store | 100.00 | 1 | 100.00 |
| 5.88 | Temperature controlled storage | 50.00 | 1 | 50.00 |
| 5.88 | Containers store | 50.00 | 1 | 50.00 |
| 5.90 | Porter's base | 5.00 | 1 | 5.00 |
| 5.90 | Clerical office | 15.00 | 1 | 15.00 |
| 5.90 | Trolley park/recharging | 5.50 | 3 | 16.50 |
| | NET TOTAL | | | 352.00 |
| | Planning | 5% | | 17.60 |
| | Sub - Total | | | 369.60 |
| | Engineering zone | 3% | | 11.09 |
| | Circulation | 12% | | 44.35 |
| | GROSS TOTAL | | | 425.04 |
| | **DEPARTMENTAL TOTAL** | | | **425.00** |

## RADIOPHARMACEUTICALS
## Schedule of Accommodation

| Para. No | Activity | SPACE AREA m² | Qty | TOTAL AREA m² |
|---|---|---|---|---|
| 4.25 | Staff wash/change/robe | 7.50 | 1 | 8.50 |
| 4.36 | Support room | 14.00 | 1 | 14.00 |
| 4.30 | Procedures room | 15.00 | 1 | 15.00 |
| 3.41 | Radioactive waste store | 2.00 | 1 | 2.00 |
| 4.71 | Pharmacist's office | 11.00 | 1 | 11.00 |
| 4.84 | Staff room | 10.00 | 1 | 10.00 |
| 4.83 | Staff W.C. | 2.00 | 2 | 4.00 |
| | Switchroom | 2.00 | 1 | 2.00 |
| | NET TOTAL | | | 66.50 |
| | Planning | 5% | | 3.33 |
| | Sub - Total | | | 69.83 |
| | Engineering zone | 3% | | 2.09 |
| | Circulation | 10% | | 6.98 |
| | GROSS TOTAL | | | 78.90 |
| | **DEPARTMENTAL TOTAL** | | | **80.00** |

## ESSENTIAL AND OPTIONAL ACCOMMODATION

### Schedule of Accommodation

| Para. No | Activity | SPACE AREA $m^2$ | Qty | AREA $m^2$ | CIRCULATION ETC. | TOTAL AREA $m^2$ |
|---|---|---|---|---|---|---|
| | **Essential Complementary Accommodation** | | | | | |
| 4.38 | In-process control laboratory | 15.00 | 1 | 15.00 | 4.00 | 19.00 |
| 4.48 | External goods entrance | 18.00 | 1 | 18.00 | 4.50 | 22.50 |
| 4.64 | Medical gas cylinders store | 27.50 | 1 | 27.50 | 7.00 | 34.50 |
| 4.78/5.57/5.80 | Cleaner's room | 7.00 | 1 | 7.00 | 2.00 | 9.00 |
| 4.79 | Staff changing | 20.00 | 1 | 20.00 | 5.00 | 25.00 |
| 4.87 | Seminar room (8 persons) | 20.00 | 1 | 20.00 | 5.00 | 25.00 |
| 4.87 | Seminar room (20 persons) | 30.00 | 1 | 30.00 | 7.50 | 37.50 |
| 4.88 | Local drug information service | 17.00 | 1 | 17.00 | 4.50 | 21.50 |
| 4.90 | Regional drug information service | | | | | |
| 4.91 | Main information work area | 36.00 | 1 | 36.00 | 9.00 | 45.00 |
| 4.91 | Quiet study area | 5.50 | 1 | 5.50 | 1.50 | 7.00 |
| 4.92 | Literature store | 7.00 | 1 | 7.00 | 2.00 | 9.00 |
| 4.92 | Pharmacist's office | 9.00 | 1 | 9.00 | 2.50 | 11.50 |
| 5.44 | Flammables store | 9.50 | 1 | 9.50 | 2.50 | 12.00 |
| 5.56/5.90 | Pharmacist's office | 9.00 | 1 | 9.00 | 2.50 | 11.50 |
| 5.61/5.80 | Staff room & beverage bay | 22.50 | 1 | 22.50 | 5.50 | 28.00 |
| 5.58/4.79 | Staff changing | 10.00 | 1 | 10.00 | 2.50 | 12.50 |
| 5.62/4.83 | Staff W.C. | 2.00 | 1 | 2.00 | 0.50 | 2.50 |
| 5.74 | Microbiological testing suite | | | | | |
| 5.75 | Test room | 14.25 | 1 | 14.25 | 3.50 | 18.00 |
| 5.76 | Ante room | 14.25 | 1 | 14.25 | 3.50 | 18.00 |
| | Switchroom | 4.00 | 1 | 4.00 | 1.00 | 5.00 |
| | **Optional Accommodation & Services** | | | | | |
| 5.88 | Secure store | 50.00 | 1 | 50.00 | 12.50 | 62.50 |
| 4.61 | Dressings store | 6.00 | 1 | 6.00 | 1.50 | 7.50 |
| 4.65 | Emergency drug store | 5.50 | 1 | 5.50 | 1.50 | 7.00 |
| 5.04 | Transfer airlock | 8.00 | 1 | 8.00 | 2.00 | 10.00 |
| 5.18 | Laundry room | 7.00 | 1 | 7.00 | 2.00 | 9.00 |
| 5.73 | Laboratory workshop | 13.00 | 1 | 13.00 | 3.50 | 16.50 |

# 10.0 Activity data

## Introduction

**10.1** Activity DataBase is an information system developed to help project and design teams by defining the users' needs more precisely. This information constitutes the computerised Activity DataBase for Windows, up-dated twice yearly.

**10.2** Room Data Sheets record in more detail than is described in this Note, each task or activity that is performed in a particular activity space, together with environmental conditions and the technical data necessary to enable the activities to be performed. Each Room Data Sheet also contains a list of relevant assembly and component codes and descriptions. Room area information is provided in conjunction with a room graphic.

**10.3** Assembly Data Sheets provide narrative text and ergonomically arranged graphics to scale relating to one activity. They show equipment fitted or supplied as part of the building, and the necessary engineering terminals.

**10.4** Component schedules provide information about the total quantities of group 1, 2 and 3 components for single data sheets or for all data sheets for a department. Group 4 components are not included in the schedule – see paragraph 1.18.

**10.5** Activity data is only available in the form of magnetic media, but users may generate paper copies where required.

**10.6** Further information about the use and preparation of activity data can be obtained from NHS Estates, Department of Health, 1 Trevelyan Square, Boar Lane, Leeds LS1 6AE.

## Activity data applicable to this Note

**10.7** The Room Data Sheets recommended for the activity spaces described in this Note are either new sheets, amended ones or ones selected from existing sheets.

**10.8** Further Room Data Sheets may be selected, or drawn up by project teams to their own requirements, for any services not described in the Note.

**10.9** In order to ensure consistent and economic provision, variations from the Room Data Sheets recommended for the spaces covered in this Note should be considered only where it has been decided that the function of a space will differ substantially from that described.

**10.10** The Room Data Sheets may not carry a title identical to the activity spaces detailed in this Note. Use of the appropriate code number will, however, result in the correct activity space being accessed.

# Appendix: Glossary

## Aseptic

Refers to procedures designed to exclude or minimise contamination by micro-organisms.

## Aseptic room

A room with a Clean Area designed, constructed, serviced and used with the intention of preventing microbial contamination of the product.

## Aseptically prepared

A product prepared using aseptic procedures..

## Clean area

A room or suite of rooms with defined environmental control of particulate and microbial contamination, constructed and used in such a way as to reduce the introduction, generation and retention of contaminants within the area.

## Controlled Drugs

Medicines and drug materials controlled under the Misuse of Drugs Act 1971 and Regulations.

## Extemporaneous preparation

Preparing products from raw materials 'according to the art', with the application of specialist skills and techniques, as and when required, rather than drawing from previously manufactured stock.

## Licensed

Possessing a licence from the Licensing Authority to operate as a manufacturer of pharmaceutical products.

## Medicines Act 1968

The primary legislation controlling preparation and dealing in medicinal products which set up a licensing system for marketed medicines and different categories of them for retail sale purposes, together with a Medicines Commission to advise Ministers.

## Original packs

Medicines packed in a form ready for use without further manipulation of the pack's contents.

## Pharmacy dispensing services

For the purpose of this Note, patient-focused activities of a hospital pharmacy such as dispensing, supply of ward drugs, information and other activities performed directly for individual patients.

## Product licence

A licence required under the Medicines Act before a medicinal product can be marketed.

## Radiopharmaceuticals

Medicinal products which achieve their purpose by virtue of radioactivity. May be used for therapy or, more commonly, diagnosis.

## Reference samples

Samples of a raw material or finished product which are held as a reference should there need to be any further testing during the shelf life of the product.

## Sterile

Containing no living organisms. For the purposes of this Note, sterile describes a material or product which has undergone a successful sterilization process and has not been subsequently contaminated.

## Support services

For the purpose of this Note, hospital pharmaceutical activities which support the pharmacy dispensing services which operate on a larger scale than supplying for an individual patient, eg manufacturing in bulk.

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53 Satellite dialysis unit, 1996

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